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Kaloo P, Armstrong S, Kaloo C, Jordan V

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Interventions to reduce shoulder pain following gynaecological laparoscopic procedures (Review)

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[Intervention Review]

Interventions to reduce shoulder pain following gynaecological laparoscopic procedures

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ABSTRACT

Background

Laparoscopy is a common procedure used to diagnose and treat various gynaecological conditions. Shoulder-tip pain (STP) as a result of the laparoscopy occurs in up to 80% of women, with potential for significant morbidity, delayed discharge and readmission. Interventions at the time of gynaecological laparoscopy have been developed in an attempt to reduce the incidence and severity of STP.

Objectives

To determine the effectiveness and safety of methods for reducing the incidence and severity of shoulder-tip pain (STP) following gynaecological laparoscopy.

Search methods

We searched the following databases: Cochrane Gynaecology and Fertility (CGF) Specialised Register, the Cochrane Central Register of Studies Online (CRSO), MEDLINE, Embase, PsycINFO and CINAHL from inception to 8 August 2018. We also searched the reference lists of relevant articles and registers of ongoing trials.

Selection criteria

Randomised controlled trials (RCTs) of interventions used during or immediately after gynaecological laparoscopy to reduce the incidence or severity of STP.

Data collection and analysis

We used standard methodological procedures expected by Cochrane. Primary outcomes: incidence or severity of STP and adverse events of the interventions; secondary outcomes: analgesia usage, delay in discharge, readmission rates, quality-of-life scores and healthcare costs.

Main results

We included 32 studies (3284 women). Laparoscopic procedures in these studies varied from diagnostic procedures to complex operations. The quality of the evidence ranged from very low to moderate. The main limitations were risk of bias, imprecision and inconsistency.

Specific technique versus "standard" technique for releasing the pneumoperitoneum

Use of a specific technique of releasing the pneumoperitoneum (pulmonary recruitment manoeuvre, extended assisted ventilation or actively aspirating intra-abdominal gas) reduced the severity of STP at 24 hours (standardised mean difference (SMD) -0.66, 95% confidence interval (CI) -0.82 to -0.50; 5 RCTs; 670 participants; $I^2 = 0\%$, low-quality evidence) and reduced analgesia usage (SMD -0.53, 95% CI -0.70 to -0.35; 4 RCTs; 570 participants; $I^2 = 91\%$, low-quality evidence). There appeared to be little or no difference in the incidence of STP at 24 hours (odds ratio (OR) 0.87, 95% CI 0.41 to 1.82; 1 RCT; 118 participants; low-quality evidence).

No adverse events occurred in the only study assessing this outcome.

Fluid instillation versus no fluid instillation

Fluid instillation is probably associated with a reduction in STP incidence (OR 0.38, 95% CI 0.22 to 0.66; 2 RCTs; 220 participants; $I^2 = 0\%$, moderate-quality evidence) and severity (mean difference (MD) (0 to 10 visual analogue scale (VAS) scale) -2.27, 95% CI -3.06 to -1.48; 2 RCTs; 220 participants; $I^2 = 29\%$, moderate-quality evidence) at 24 hours, and may reduce analgesia usage (MD -12.02, 95% CI -23.97 to -0.06; 2 RCTs; 205 participants, low-quality evidence).

No study measured adverse events.

Intraperitoneal drain versus no intraperitoneal drain

Using an intraperitoneal drain may reduce the incidence of STP at 24 hours (OR 0.30, 95% CI 0.20 to 0.46; 3 RCTs; 417 participants; $I^2 = 90\%$, low-quality evidence) and may reduce analgesia use within 48 hours post-operatively (SMD -1.84, 95% CI -2.14 to -1.54; 2 RCTs; 253 participants; $I^2 = 90\%$). We are uncertain whether it reduces the severity of STP at 24 hours, as the evidence was very low quality (MD (0 to 10 VAS scale) -1.85, 95% CI -2.15 to -1.55; 3 RCTs; 320 participants; $I^2 = 70\%$).

No study measured adverse events.

Subdiaphragmatic intraperitoneal local anaesthetic versus control (no fluid instillation, normal saline or Ringer's lactate)

There is probably little or no difference between the groups in incidence of STP (OR 0.72, 95% CI 0.42 to 1.23; 4 RCTs; 336 participants; $I^2 = 0\%$; moderate-quality evidence) and there may be no difference in STP severity (MD -1.13, 95% CI -2.52 to 0.26; 1 RCT; 50 participants; low-quality evidence), both measured at 24 hours. However, the intervention may reduce post-operative analgesia use (SMD -0.57, 95% CI -0.94 to -0.21; 2 RCTs; 129 participants; $I^2 = 51\%$, low-quality evidence).

No adverse events occurred in any study.

Local anaesthetic into peritoneal cavity (not subdiaphragmatic) versus normal saline

Local anaesthetic into the peritoneal cavity may reduce the incidence of STP at 4 to 8 hours post-operatively (OR 0.23, 95% CI 0.06 to 0.93; 2 RCTs; 157 participants; $I^2 = 56\%$; low-quality evidence). Our other outcomes of interest were not assessed.

Warmed, or warmed and humidified CO₂ versus unwarmed and unhumidified CO₂

There may be no difference between these interventions in incidence of STP at 24 to 48 hours (OR 0.81 95% CI 0.45 to 1.49; 2 RCTs; 194 participants; $I^2 = 12\%$; low-quality evidence) or in analgesia usage within 48 hours (MD -4.97 mg morphine, 95% CI -11.25 to 1.31; 1 RCT; 95 participants; low-quality evidence); there is probably little or no difference in STP severity at 24 hours (MD (0 to 10 VAS scale) 0.11, 95% CI -0.75 to 0.97; 2 RCTs; 157 participants; $I^2 = 50\%$; moderate-quality evidence).

No study measured adverse events.

Gasless laparoscopy versus CO₂ insufflation

Gasless laparoscopy may be associated with increased severity of STP within 72 hours post-operatively when compared with standard treatment (MD 3.8 (0 to 30 VAS scale), 95% CI 0.76 to 6.84; 1 RCT; 54 participants, low-quality evidence), and there may be no difference in the risk of adverse events (OR 2.56, 95% CI 0.25 to 26.28; 1 RCT; 54 participants; low-quality evidence).

No study measured the incidence of STP.

Authors' conclusions

There is low to moderate-quality evidence that the following interventions are associated with a reduction in the incidence or severity, or both, of STP, or a reduction in analgesia requirements for women undergoing gynaecological laparoscopy: a specific technique for releasing the pneumoperitoneum; intraperitoneal fluid instillation; an intraperitoneal drain; and local anaesthetic applied to the peritoneal cavity (not subdiaphragmatic).

There is low to moderate-quality evidence that subdiaphragmatic intraperitoneal local anaesthetic and warmed and humidified insufflating gas may not make a difference to the incidence or severity of STP.

There is low-quality evidence that gasless laparoscopy may increase the severity of STP, compared with standard treatment.

Few studies reported data on adverse events. Some potentially useful interventions have not been studied by RCTs of gynaecological laparoscopy.

PLAIN LANGUAGE SUMMARY

Methods to reduce shoulder pain after gynaecological keyhole surgery

Review question

Cochrane authors wanted to find out how effective different methods (interventions) are in reducing the amount and severity of shoulder pain following gynaecological keyhole surgery.

Background

Gynaecological keyhole surgery (laparoscopy) is a procedure where a surgeon uses a camera (laparoscope) to see inside the lower abdomen to view the uterus (womb), fallopian tubes and ovaries. They can also use special instruments to do tests or treat certain gynaecological conditions. This is a common procedure that about 250,000 women in the UK have each year. Up to 80% of these women may experience shoulder-tip pain (STP), which may be very painful and lead to longer stays in hospital and even having to go back in to hospital.

During the laparoscopy, the surgeon puts gas (carbon dioxide) into the patient's abdomen (pneumoperitoneum). This inflates the abdomen so that the surgeon can see the organs in the abdominal cavity and can carry out surgery. It is possible that inflating the abdomen stimulates a nerve that runs from the top of the abdomen (diaphragm) up to the shoulders and neck, which causes STP.

We looked at several ways surgeons try to reduce STP: putting local anaesthetic (pain killer) directly into the abdominal cavity or diaphragm; using warmed carbon dioxide, sometimes with moisture added to it (humidified) during surgery; removing gas from the abdominal cavity with drains; replacing gas with fluid (fluid instillation) or forcing gas out of the abdominal cavity at the end of the procedure by increasing the pressure at which patients were made to breathe whilst still under anaesthetic (PRM).

Study characteristics

Our evidence comes from 32 randomised controlled trials (clinical studies where people are randomly put into one of two or more treatment groups) with 3284 women from 11 countries. The trials compared different ways of reducing the incidence (number of times STP occurred) or severity of STP in women undergoing gynaecological laparoscopy. The evidence is up to date to 8 August 2018.

Key results

Women having gynaecological laparoscopy may have less STP or need fewer pain killers following several interventions: a specific technique for releasing the pneumoperitoneum; leaving fluid or local anaesthetic (liquid pain killers) in the abdomen or putting a drain from the inside to the outside of the abdomen for a period of time.

There is low to moderate-quality evidence that the following interventions may not make a difference to the incidence or severity of STP: local anaesthetic (liquid pain killers) placed only in the upper part of the abdomen underneath the diaphragm; warmed and moistened carbon dioxide gas.

There is low-quality evidence that gasless laparoscopy may increase the severity of STP, compared with standard treatment.

Few studies reported side effects (adverse events) and some potentially useful interventions have not been studied by RCTs of gynaecological laparoscopy.

We are cautious about these results because the evidence from the studies that we found was not good quality (low to moderate-quality evidence).

Quality of the evidence

The studies in this review did not use the best methods to gather and report their evidence and we thought the evidence was only low to moderate quality. This means that we cannot be very confident in the results.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Specific technique compared to standard technique for releasing the pneumoperitoneum for the reduction of shoulder pain following gynaecological laparoscopic procedures

Specific technique compared to standard technique for releasing the pneumoperitoneum for the reduction of shoulder pain following gynaecological laparoscopic procedures

Patient or population: women undergoing a diagnostic or operative laparoscopic gynaecological procedure

Setting: surgical

Intervention: specific technique

Comparison: standard technique for releasing the pneumoperitoneum

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with standard technique for releasing the pneumoperitoneum	Risk with Specific technique				
Incidence of STP at 24 hours post-operatively	627 per 1000	594 per 1000 (408 to 754)	OR 0.87 (0.41 to 1.82)	118 (1 RCT)	⊕⊕⊕⊕ Low ^{1, 2}	
Severity of STP at 24 hours post-operatively	The mean severity of post-operative STP at 24 hours ranged from 2.6 to 5.4 on a 0-10 scale (higher score worse)	SMD 0.66 SD lower (0.82 lower to 0.50 lower)	-	670 (5 RCTs)	⊕⊕⊕⊕ Low ³	
Adverse events	0 per 1000	0 per 1000 (0 to 0)	not estimable	74 (1 study)	-	
Analgesia usage during study follow-up	Mean analgesia usage ranged from 3.71 (mg piritramide) to 112.5 (mg diclofenac)	SMD 0.53 lower (0.70 lower to 0.35 lower)	-	570 (4 RCTs)	⊕⊕⊕⊕ Low ^{4, 5}	

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** Odds ratio; **RCT:** randomised controlled trial; **SMD:** standardised mean difference; **STP:** shoulder-tip pain

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

- ¹Downgraded one level for high risk of bias; high risk of performance and detection bias owing to lack of blinding in one study.
²Downgraded one level for imprecision; single study with relatively small numbers of participants.
³Downgraded two levels for risk of bias; high risk of 'other' bias within one study, and high reporting, detection and performance bias across studies.
⁴Downgraded one level for high risk bias; high risk of 'other' bias in one included study owing to difference in the mean duration of surgery and volume of CO₂ used.
⁵Downgraded one level for inconsistency; evidence of heterogeneity.

Summary of findings 2. Fluid instillation compared to no fluid instillation for the reduction of shoulder pain following gynaecological laparoscopic procedures

Fluid instillation compared to no fluid instillation for the reduction of shoulder pain following gynaecological laparoscopic procedures

Patient or population: women undergoing a diagnostic or operative laparoscopic gynaecological procedure

Setting: surgical

Intervention: fluid instillation

Comparison: no fluid instillation

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with no fluid instillation	Risk with fluid instillation				
Incidence of STP at 24 hours post-operatively	649 per 1000	412 per 1000 (289 to 549)	OR 0.38 (0.22 to 0.66)	220 (2 RCTs)	⊕⊕⊕⊖ Moderate ¹	
Severity of STP at 24 hours post-operatively	The mean severity of STP at 24 hours post-operatively ranged from 4.22 to 4.52 (10-point VAS, higher score worse)	MD 2.27 (10-point VAS) lower (3.06 lower to 1.48 lower)	-	205 (2 RCTs)	⊕⊕⊕⊖ Moderate ¹	
Adverse events	Not assessed by any study	-	-	-	-	
Analgesia usage (meperidine mg) within 24 hours post-operatively	The mean analgesia usage (meperidine mg) ranged from 62.8 to 115.2	MD 12.02 lower (23.97 lower to 0.06 lower)	-	205 (2 RCTs)	⊕⊕⊖⊖ Low ^{1,2}	

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** Odds ratio; **STP:** shoulder-tip pain; **VAS:** visual analogue scale

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

¹Downgraded one level for risk of bias; high performance and detection bias in one study owing to lack of blinding.

²Downgraded one level for imprecision due to broad confidence intervals and imprecise result.

Summary of findings 3. Intraperitoneal drain compared to no intraperitoneal drain for the reduction of shoulder pain following gynaecological laparoscopic procedures

Intraperitoneal drain compared to no intraperitoneal drain for the reduction of shoulder pain following gynaecological laparoscopic procedures

Patient or population: women undergoing a diagnostic or operative laparoscopic gynaecological procedure

Setting: surgical

Intervention: intraperitoneal drain

Comparison: no intraperitoneal drain

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with no intraperitoneal drain	Risk with intraperitoneal drain				
Incidence of STP at 24 hours post-operatively	474 per 1000	213 per 1000 (153 to 293)	OR 0.30 (0.20 to 0.46)	417 (3 RCTs)	⊕⊕⊕⊕ Low ^{1, 2}	
Severity of STP at 24 hours post-operatively	The mean severity of STP at 24 hours ranged from 3.2 to 3.9 (10-point VAS, higher score worse)	MD 1.85 (10-point VAS) lower (2.15 lower to 1.55 lower)	-	320 (3 RCTs)	⊕⊕⊕⊕ Very low ^{2, 3}	
Adverse events	Not assessed by any study	-	-	-	-	
Analgesia usage within 48 hours post-operatively	Mean analgesia usage ranged from 2.8 doses of 100 mg diclofenac to 12.4 mg paracetamol	SMD 1.84 lower (2.14 lower to 1.54 lower)	-	253 (2 RCTs)	⊕⊕⊕⊕ Low ^{1, 2}	

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** Odds ratio; **SMD:** standardised mean difference; **STP:** shoulder-tip pain; **VAS:** visual analogue scale

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

¹Downgraded one level for risk of bias; high performance and detection bias owing to lack of blinding.

²Downgraded one level for inconsistency; evidence of heterogeneity between studies.

³Downgraded two levels for risk of bias; high performance and detection bias owing to lack of blinding, and due to high risk of 'other' bias owing to unbalanced major operative procedures between groups.

Summary of findings 4. Subdiaphragmatic intraperitoneal local anaesthetic compared to control for the reduction of shoulder pain following gynaecological laparoscopic procedures

Subdiaphragmatic intraperitoneal local anaesthetic compared to control for the reduction of shoulder pain following gynaecological laparoscopic procedures

Patient or population: women undergoing a diagnostic or operative laparoscopic gynaecological procedure

Setting: surgical

Intervention: subdiaphragmatic intraperitoneal local anaesthetic

Comparison: control (no fluid, 0.9% saline or Ringer's lactate)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with control	Risk with subdiaphragmatic intraperitoneal local anaesthetic				
Incidence of STP at 24 hours post-operatively	282 per 1000	220 per 1000 (141 to 325)	OR 0.72 (0.42 to 1.23)	336 (4 RCTs)	⊕⊕⊕⊖ Moderate ¹	
Severity of STP at 24 hours post-operatively	The mean severity of post-operative STP at 24 hours was 2.42 (10-point VAS, higher score worse)	MD 1.13 (10-point VAS) lower (2.52 lower to 0.26 higher)	-	50 (1 RCT)	⊕⊕⊖⊖ Low ^{2, 3}	
Adverse events	No events reported in either arm of any study		-	165 (3 studies)	-	
Analgesia usage within 24-48 hours post-operatively	Mean analgesia usage ranged from 5 (doses of 500 mg paracetamol) to 41.94 (mg meperidine)	SMD 0.57 lower (0.94 lower to 0.21 lower)	-	129 (2 RCTs)	⊕⊕⊖⊖ Low ^{1, 4}	

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; MD: mean difference; OR: Odds ratio; SMD: standardised mean difference; STP: shoulder-tip pain; VAS: visual analogue scale

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

¹Downgraded one level for risk of bias; high or unclear reporting bias detected in all studies.

²Downgraded one level for risk of bias; unclear selection, performance and detection bias.

³Downgraded one level for imprecision; broad confidence intervals within single study with small participant numbers.

⁴Downgraded one level for inconsistency; evidence of heterogeneity in results.

Summary of findings 5. Local anaesthetic to peritoneal cavity (not subdiaphragmatic) compared to control for the reduction of shoulder pain following gynaecological laparoscopic procedures

Local anaesthetic to peritoneal cavity (not subdiaphragmatic) compared to control for the reduction of shoulder pain following gynaecological laparoscopic procedures

Patient or population: women undergoing gynaecological laparoscopic procedures

Setting: hospital surgical unit

Intervention: local anaesthetic to peritoneal cavity (not subdiaphragmatic)

Comparison: normal saline to peritoneal cavity (not subdiaphragmatic)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with control	Risk with local anaesthetic to peritoneal cavity (not subdiaphragmatic)				
Incidence of STP within 4-8 hours post-operatively	117 per 1000	30 per 1000 (8 to 110)	OR 0.23 (0.06 to 0.93)	157 (2 RCTs)	⊕⊕⊕⊖ Low ^{1,2}	No data available at 24-hour follow-up
Severity of STP	Not assessed by either study		-	-	-	
Adverse events	Not assessed by either study		-	-	-	
Analgesia usage	Not assessed by either study		-	-	-	

*The basis for the **assumed risk** is the mean control group risk across studies. **The corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; OR: Odds ratio; STP: shoulder-tip pain

GRADE Working Group grades of evidence

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

¹Downgraded one level for risk of bias; high or unclear risk of reporting bias in all studies.

²Downgraded one level for inconsistency; evidence of substantial heterogeneity in results.

Summary of findings 6. Warmed, or warmed and humidified CO₂ compared to unwarmed and unhumidified CO₂ for the reduction of shoulder pain following gynaecological laparoscopic procedures

Warmed, or warmed and humidified CO₂ compared to unwarmed and unhumidified CO₂ for the reduction of shoulder pain following gynaecological laparoscopic procedures

Patient or population: women undergoing gynaecological laparoscopic procedures

Setting: surgical

Intervention: warmed +/- humidified CO₂

Comparison: unwarmed and unhumidified CO₂

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with unwarmed and unhumidified CO ₂	Risk with warmed +/- humidified CO ₂				
Incidence of STP within 24-48 hours post-operatively	549 per 1000	496 per 1000 (354 to 644)	OR 0.81 (0.45 to 1.49)	194 (2 RCTs)	⊕⊕⊕⊕ Low ^{1,2}	No data available at 24-hour follow-up
Severity of STP at 24 hours post-operatively	The mean severity of STP at 24 hours post-operatively ranged from 1.61 to 2.1 (10 point VAS, higher score worse)	MD 0.11 (10-point VAS) higher (0.75 lower to 0.97 higher)	-	157 (2 RCTs)	⊕⊕⊕⊕ Moderate ²	
Adverse events	Not assessed by any study	-	-	-	-	

Analgesia usage (morphine mg) over 48 hours post-operatively	The mean analgesia usage (morphine mg) was 15.17	MD 4.97 lower (11.25 lower to 1.31 higher)	-	95 (1 RCT)	⊕⊕⊕⊕ Low ³
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***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** Odds ratio; **STP:** shoulder-tip pain; **VAS:** visual analogue scale

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

¹Downgraded one level for risk of bias; high risk of reporting and 'other' bias in one study owing to interim data analysis and study being terminated prematurely as a result.

²Downgraded one level for imprecision; broad confidence intervals and small number of studies.

³Downgraded two levels for imprecision; single small study with very broad confidence intervals.

Summary of findings 7. Gasless laparoscopy compared to CO₂ insufflation for the reduction of shoulder pain following gynaecological laparoscopic procedures

Gasless laparoscopy compared to CO₂ insufflation for the reduction of shoulder pain following gynaecological laparoscopic procedures

Patient or population: women undergoing gynaecological laparoscopic procedures

Setting: hospital surgical unit

Intervention: gasless laparoscopy

Comparison: CO₂ insufflation

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with CO ₂ insufflation	Risk with gasless laparoscopy				
Incidence of STP	Not assessed by this study					
Severity of STP over 72 hours post-operatively	The mean severity of STP over 72 hours post-operatively was 4.4 (30-point VAS, higher score worse)	MD 3.8 (30-point VAS) higher (0.76 higher to 6.84 higher)	-	54 (1 RCT)	⊕⊕⊕⊕ Low ^{1, 2}	No 24-hour data reported
Adverse events	42 per 1000	100 per 1000	OR 2.56	54	⊕⊕⊕⊕	

	(11 to 533)	(0.25 to 26.28)	(1 study)	Low ^{1, 2}
Analgesia usage	Not assessed by this study			

*The basis for the **assumed risk** is the mean control group risk across studies. **The corresponding risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **OR:** Odds ratio; **MD:** mean difference; **STP:** shoulder-tip pain; **VAS:** visual analogue scale

GRADE Working Group grades of evidence

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

¹Downgraded one level for risk of bias; high risk of reporting bias.

²Downgraded one level for imprecision; single small study with broad confidence intervals.

BACKGROUND

Laparoscopy is a commonplace procedure in gynaecological surgery. A common complaint following laparoscopy is shoulder-tip pain (STP), which is a result of irritation of the phrenic nerve causing referred pain to the shoulder. The reported incidence varies from 35% (Dobbs 1987) to 80% (Demco 2001). It may be associated with significant patient morbidity secondary to the pain severity. The pain may last up to three days and is often rated as worse than the pain from the actual procedure. This can result in increased analgesia use (Kafali 2004), slower recovery, slower discharge from hospital and, rarely, re-admission (Alexander 1997).

Description of the condition

The generally accepted cause of STP following any laparoscopic procedure is that diaphragmatic phrenic nerve irritation causes referred pain to the shoulder area (Riedel 1980).

Numerous aetiologies have been proposed for the underlying cause of phrenic nerve irritation and subsequent STP, none of which can alone explain the phenomenon. It is therefore assumed that it is multifactorial in nature.

Suggested aetiologies include the following.

- **Carbonic acid production.** It has been proposed that carbon dioxide within the peritoneal cavity undergoes transformation into carbonic acid by the action of peritoneal carbonic anhydrase (Riedel 1980). A reduction in the peritoneal pH causes direct damage or irritation of the diaphragmatic peritoneal nerves and thus pain. This theory is supported by a randomised controlled trial (RCT) using the carbonic anhydrase inhibitor acetazolamide. It is not supported, however, by another RCT that showed no statistically significant correlation with peritoneal fluid pH and STP scores (Perry 1993). It also does not explain the presence of STP when other 'non-acid producing' gas media such as nitrous oxide are used (Lipscomb 1994), when no gas is used at all (manual abdominal wall lifting), the 'positional' nature of the pain (Phelps 2008) and the normal onset of STP being several hours post-procedure.
- **Microvascular peritoneal haemorrhages.** When the pelvic peritoneal surface is stretched, traction and tearing of microvascular structures may occur with subsequent haemorrhage. This haemorrhage may be microscopic or macroscopic but can cause pain due to the release of inflammatory mediators and cell contents, which may be directly or indirectly noxious (Abbott 2001; Mouton 1999). This could explain the incidence of STP in gasless laparoscopy being similar to that seen with routine carbon dioxide insufflation. It may also explain the findings that higher insufflation pressures are related to higher incidences of STP (Berberoglu 1999; Sarli 2000).
- **Peritoneal dehydration and damage.** This may occur because of the drying effect of cold, dry insufflation gases (Ott 1998). The evidence for this is contradictory, with no clear benefit on the incidence or severity of STP with humidification or warming of insufflating gases, or both (Demco 2001; Korell 1996).
- **Visceral ligament traction.** Another theory is that the presence of intra-abdominal gas causes the loss of a 'suction' effect between the liver and diaphragm, allowing traction on the triangular and coronary ligaments of the liver that leads to

subdiaphragmatic pain and STP (Dobbs 1987; Perry 1993). There is little direct evidence supporting this but it is indirectly supported by several observations: the positional nature of STP, occurring when women are sitting up and mobilising (Perry 1993); the time scale of onset of pain being generally being more than four hours post-procedure; the presence of STP in gasless laparoscopy, with residual room air being present (Goldberg 1991; Guido 1998; Johnson 1997); and finally the direct 'relation' between the amount of residual gas and STP (Jackson 1996) being the degree of the loss of the 'suction' effect between the liver and diaphragm.

- **Neuropraxia.** The direct stretching of the phrenic nerve fibres within the diaphragm could induce referred pain. There is little direct evidence for this. From a physiological perspective this may not be a major contributory factor. The phrenic nerve's sensory innervation of the diaphragm is almost entirely restricted to the central tendon, which is relatively rigid and inelastic with normal physiological stresses (Aladin 1997). This relatively inelastic structure would theoretically be more likely to splint the nerves and reduce the likelihood of neuropraxia. However, possible indirect evidence is the suggestion that increased intra-abdominal pressure (hence more peritoneal and therefore nerve 'stretching') during laparoscopy is associated with an increased incidence of STP (Gurusamy 2007).

There are other reported causes of STP that may follow laparoscopy and these include arm abduction (Kojima 2004) and the use of succinylcholine (a muscle relaxant) and the associated post-operative muscle pain (Smith 1993).

This review will look at all the available randomised controlled trials that have investigated methods of preventing or reducing post-laparoscopy STP for gynaecological procedures.

Description of the intervention

Laparoscopy is the surgical procedure by which the peritoneal cavity is accessed via small incisions in the abdominal wall. Via these incisions, direct visualisation of abdominal and pelvic structures can occur with the use of specific narrow optical instruments (laparoscopes). With additional entry points ('port sites') in the abdominal wall, operative procedures can be undertaken. The process of laparoscopy generally requires general anaesthesia, although it can be undertaken under local anaesthesia in specific situations (Demco 2001).

The initial step of a laparoscopy is the distension of the abdominal cavity to allow adequate visualisation of the organs contained within. Distension usually involves using a gas medium ('pneumoperitoneum'), most commonly carbon dioxide. Carbon dioxide is preferred as it is inert and does not support combustion; it is absorbed relatively rapidly through the peritoneal surfaces and is readily available and, consequently, cheap. The carbon dioxide is generally insufflated into the peritoneal cavity by the blind placement of a 'Veress' needle through the umbilicus. After this, the port is inserted through which the laparoscope is placed and a variable number of accessory ports are made if required.

Other techniques have been used to distend the abdominal cavity, which have involved instruments that physically lift the abdominal wall (Guido 1998).

Various techniques have been used to reduce the incidence and severity of STP, often with inconsistent findings. These include the use of gasless laparoscopy (Guido 1998), low gas pressures (Sarli 2000), an alternative insufflating gas, warmed or humidified insufflating gas (Manwaring 2008), use of intra-abdominal drains (Abbott 2001), intraperitoneal anaesthetic or fluid instillation (Narchi 1991; Ozer 2005) and specific techniques for releasing the pneumoperitoneum, such as manually forcing gas out of the abdominal incisions at the end of the procedure (Kafali 2004; Phelps 2008; Sharami 2010). The 'standard' or usual care for reducing STP is the manual compression of the abdomen at the end of the procedure with the laparoscopic ports left open. The aim being to expel as much residual carbon dioxide as possible.

How the intervention might work

The interventions described previously are postulated to work in various ways, by either removing as much carbon dioxide or gas as possible post-procedure (use of intra-abdominal drains for a variable duration post-operatively, specific techniques for releasing the pneumoperitoneum (such as manual pressure on the abdomen), by not using carbon dioxide at all (gasless laparoscopy), by using a gas other than carbon dioxide or by reducing phrenic nerve irritation (low gas pressure, warmed or humidified gas).

Why it is important to do this review

Approximately 250,000 women in the UK undergo a gynaecological laparoscopy each year. STP is a very common post-laparoscopy complication with potentially significant morbidity (pain) as well as healthcare costs in relation to delayed recovery and discharge, and increased analgesia usage (Alexander 1997; Kafali 2004). At present there is no consensus amongst gynaecologists as to what can be done intra- and post-operatively to prevent or reduce the severity of this symptom. As such, a systematic review can help clinicians with an evidence-based cost-effective approach to preventing STP in their patients (Abbott 2001).

OBJECTIVES

To determine the effectiveness and safety of methods for reducing the incidence and severity of shoulder-tip pain (STP) following gynaecological laparoscopy.

METHODS

Criteria for considering studies for this review

Types of studies

Published and unpublished randomised controlled trials (RCTs) were eligible for inclusion with explicit or presumed participant blinding and that involved an intervention to reduce post-laparoscopic STP in patients undergoing a gynaecological procedure. We excluded non-randomised studies (for example studies with evidence of inadequate sequence generation such as alternate days, patient numbers) as they are associated with a high risk of bias.

Types of participants

Inclusion criteria: women undergoing a diagnostic or operative laparoscopic procedure (gynaecological)

Exclusion criteria: women who subsequently underwent a laparotomy; women who experienced a major intra-operative complication relating to vascular, bowel or bladder injury leading to phrenic nerve irritation.

Types of interventions

The 'standard' or usual care for undertaking a laparoscopy is to insufflate the abdominal cavity with unhumidified, unwarmed carbon dioxide at a pressure of 20 mmHg to 25 mmHg then reduce the insufflation pressure to 12 mmHg to 15 mmHg when all ports have been placed. The 'standard' or usual care for specifically reducing STP is manual compression of the abdomen at the end of the procedure with the laparoscopic ports left open, the aim being to expel as much residual carbon dioxide as possible.

The types of interventions investigated were those additional or alternative steps that were utilised before, during or after a gynaecological laparoscopic procedure to reduce the incidence or severity of STP. We excluded studies that investigated the administration of oral, intravenous, subcutaneous or intramuscular analgesia or other medications.

The following study interventions were eligible.

Medical methods:

- use of intraperitoneal anaesthetic or fluid instillation;
- use of humidified or warmed insufflating gas, or both;
- use of gasless laparoscopy.

Physical methods:

- use of intraperitoneal drains;
- use of forced gas evacuation: manually, fluid displacement or inflation breaths;
- use of postural changes (nursing women with a head-down tilt immediately post-operatively).

Types of outcome measures

Primary outcomes

- Incidence (number of women experiencing STP within one week of surgery) or severity of shoulder pain (as measured by a visual analogue scale or dichotomous data within one week of surgery)
- Any adverse outcome that was likely to be directly attributable to the intervention utilised in the study

Secondary outcomes

- Analgesia usage
- Delay in discharge (attributable to STP)
- Readmission rates (attributable to STP)
- Quality-of-life scores
- Directly related healthcare costs

Search methods for identification of studies

We searched all published and unpublished RCTs of interventions for reducing STP following gynaecological laparoscopy, without language restriction and in consultation with the Cochrane Gynaecology and Fertility (CGF) Information Specialist.

Electronic searches

We searched the following electronic databases, trials registers and websites from their inception to 8 August 2018:

- the Cochrane Gynaecology and Fertility Group (CGF) Specialised Register of controlled trials; PROCITE platform searched 8 August 2018 ([Appendix 1](#));
- the Cochrane Central Register of Studies Online (CRSO); Web platform searched 8 August 2018 ([Appendix 2](#));
- MEDLINE; OVID platform searched from 1946 to 8 August 2018 ([Appendix 3](#));
- Embase; OVID platform searched from 1980 to 8 August 2018 ([Appendix 4](#));
- PsycINFO; OVID platform searched from 1806 to 8 August 2018 ([Appendix 5](#));
- CINAHL; EBSCO platform searched from 1961 to 8 August 2018 ([Appendix 6](#)).

Other electronic sources of studies included:

- trials registers for ongoing and registered studies (www.controlled-trials.com; <http://clinicaltrials.gov/ct2/home>; www.who.int/trialsearch/Default.aspx);
- citation indexes (scientific.thomson.com/products/sci/);
- conference abstracts and studies in the Web of Science (wokinfo.com/);

- LILACS database for studies from the Portuguese- and Spanish-speaking world (<http://lilacs.bvsalud.org/>);
- PubMed (www.ncbi.nlm.nih.gov/pubmed/) and Google for any papers that have been published but not yet indexed in the major databases;
- OpenGrey database (www.opengrey.eu/) and Google Scholar.

Searching other resources

We handsearched reference lists of articles retrieved by the search and contact experts in the field to obtain additional data. We also handsearched relevant journals and conference abstracts that were not covered in the CGF Specialised Register, in liaison with the Information Specialist.

Data collection and analysis

We collected and analysed data in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011a](#)).

Selection of studies

Marian Showell, CGF Information Specialist, undertook the search strategies for this review. SA and PK independently screened titles and abstracts retrieved by the search. We retrieved the full texts of all potentially eligible studies and SA and PK independently examined them for compliance with the inclusion criteria. We corresponded with study authors, as required, to clarify study eligibility and resolved any disagreements as to study eligibility by discussion. The flow of studies through the selection process is documented with a PRISMA flow chart ([Figure 1](#); [Moher 2009](#)).

Figure 1. PRISMA flow chart

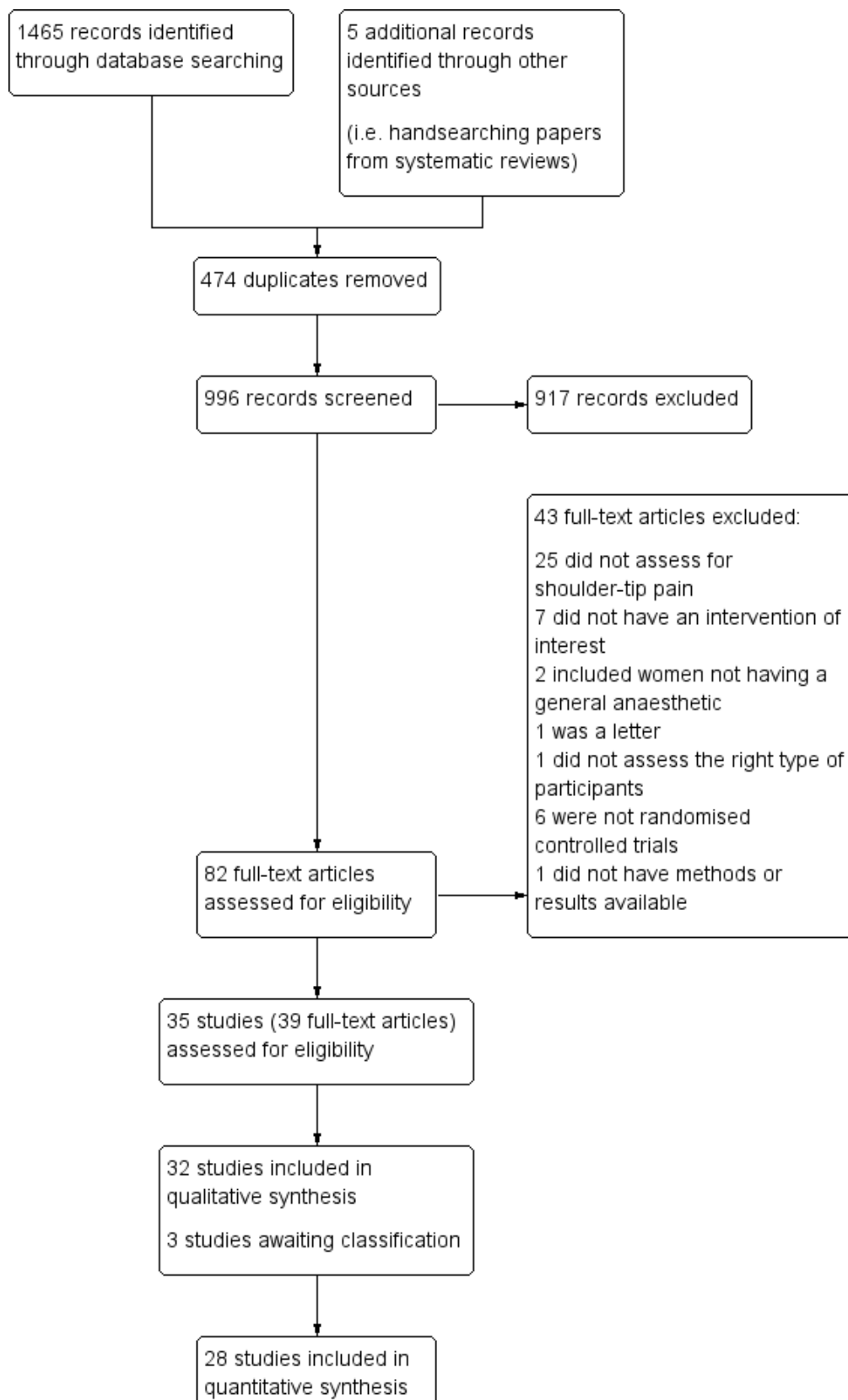


Figure 1. (Continued)

20 studies included in quantitative synthesis (meta-analysis)

Data extraction and management

SA and PK independently extracted data from the eligible studies using a data extraction form designed and pilot-tested by the review authors. We resolved any disagreements by discussion or by involving a third review author. The data that we extracted included study characteristics, which are set out in the 'Characteristics of studies' tables.

Where studies had multiple publications, we used the main study report as the reference, and derived additional details from the secondary papers. We corresponded with study authors to obtain further data on methods or results, or both, as required.

Assessment of risk of bias in included studies

PK and SA independently assessed the included studies for risk of bias using the Cochrane 'Risk of bias' assessment tool (Higgins 2011b), to assess: allocation (random sequence generation and allocation concealment); blinding of participants and personnel; blinding of outcome assessors; incomplete outcome data; selective reporting; and other bias. We resolved disagreements by discussion. We described all judgements fully and we have presented the conclusions in the 'Risk of bias' tables. The 'Risk of bias' assessments were incorporated into the interpretation of review findings by means of sensitivity analyses.

We took care to search for within-study selective reporting, such as studies failing to report obvious outcomes or reporting them in insufficient detail to allow inclusion. We sought published protocols, and requested them from study authors where necessary, to compare outcomes between the protocol and the final published study.

Measures of treatment effect

For dichotomous data (for example STP present or absent), we used the numbers of events in the control and intervention groups of each study to calculate Mantel-Haenszel odds ratios (ORs). For continuous data, if all studies reported exactly the same outcomes we calculated the mean difference (MD) between treatment groups. If similar outcomes were reported on different scales we calculated the standardised mean difference (SMD). We reversed the direction of effect of individual studies, if required, to ensure consistency across studies. We treated ordinal data (for example quality-of-life scores) as continuous data. We presented 95% confidence intervals (CIs) for all outcomes. Where data to calculate ORs or MDs were not available, we utilised the most detailed numerical data available that facilitated similar analyses of included studies (for example percentages of participants, test statistics, P values). We have compared the magnitude and direction of effect reported by studies with how they are presented in the review, taking account of legitimate differences.

Unit of analysis issues

The primary analysis was per woman randomised. Where possible we have undertaken intention-to-treat analyses within dichotomous

outcome data. Where data were not available for all randomised participants, we included only the available data.

Dealing with missing data

We analysed the data on an intention-to-treat basis as far as possible and attempted to obtain missing data from the original study lists. However, attempts at obtaining data from participants who dropped out, or committed protocol violations were unsuccessful.

Assessment of heterogeneity

We considered whether the clinical and methodological characteristics of the included studies were sufficiently similar for meta-analysis to provide a clinically meaningful summary. We assessed statistical heterogeneity by the measure of the I^2 statistic (Higgins 2003). An I^2 value greater than 50% was taken to indicate substantial heterogeneity (Higgins 2011a).

Assessment of reporting biases

In view of the difficulty of detecting and correcting for publication bias and other reporting biases, we aimed to minimise their potential impact by ensuring a comprehensive search for eligible studies and by being alert for duplication of data. There were never 10 or more studies in an analysis, therefore we were unable to use a funnel plot to explore the possibility of small study effects (Sterne 2011).

Data synthesis

When the studies were sufficiently similar, we combined the data using a fixed-effect model in the following comparisons.

- Specific technique for releasing the pneumoperitoneum versus 'standard' technique for releasing the pneumoperitoneum
- Fluid instillation versus no fluid instillation, stratified by volume and site of instillation according to study characteristics
- Intraperitoneal drain versus no use of intraperitoneal drain
- Subdiaphragmatic intraperitoneal local anaesthetic versus control
- Local anaesthetic to peritoneal cavity (not subdiaphragmatic) versus control
- Warmed, or warmed and humidified insufflating gas versus unwarmed and non-humidified insufflation gas
- Gasless laparoscopy versus carbon dioxide insufflation
- Alternative insufflating gas versus carbon dioxide insufflation

Subgroup analysis and investigation of heterogeneity

Where data were available, we conducted subgroup analyses to determine the separate evidence within the following subgroups.

- The extent of surgery: minor (e.g. diagnostic laparoscopy) or major (e.g. operative laparoscopy)

- The various different interventions for 'specific technique for releasing the pneumoperitoneum' and 'warmed, or warmed and humidified carbon dioxide'. For example, we were able to subgroup 'pulmonary recruitment manoeuvre' studies and 'warmed and humidified carbon dioxide' studies owing to the volume of studies assessing these particular interventions.

If we detected substantial heterogeneity, we explored possible explanations with sensitivity analyses. We undertook any statistical heterogeneity into account when interpreting the results, especially if there was any variation in the direction of effect.

Sensitivity analysis

We conducted sensitivity analyses for the primary outcomes to determine whether the conclusions were robust to arbitrary decisions made regarding the eligibility and analysis of studies. These analyses included consideration of whether the review conclusions would have differed if:

- eligibility were restricted to studies without high risk of bias (e.g. studies at high risk of bias in any domain);
- a random-effects model had been adopted;
- the summary effect measure was risk ratio rather than odds ratio.

Overall quality of the body of evidence: 'Summary of findings' table and GRADE

We prepared 'Summary of findings' tables using GRADEpro software (GRADEpro GDT 2015). These tables evaluate the overall quality of the body of evidence for the main review outcomes (incidence or severity of shoulder pain, any adverse outcome that was directly attributable to the intervention utilised in the study and analgesia usage) for the main review comparison (specific technique compared to standard technique for releasing the pneumoperitoneum for the reduction of shoulder pain following gynaecological laparoscopic procedures). Where data were available, we reported pain outcomes at 24 hours post-operative follow-up.

We prepared additional 'Summary of findings' tables for other important comparisons (fluid instillation compared to no fluid instillation for the reduction of shoulder pain following gynaecological laparoscopic procedures; intraperitoneal drain compared to no intraperitoneal drain for the reduction of shoulder pain following gynaecological laparoscopic procedures; subdiaphragmatic intraperitoneal local anaesthetic compared to control for the reduction of shoulder pain following gynaecological laparoscopic procedures; local anaesthetic to peritoneal cavity (not subdiaphragmatic) compared to control for the reduction of shoulder pain following gynaecological laparoscopic procedures; warmed, or warmed and humidified carbon dioxide compared to unwarmed and unhumidified carbon dioxide for the reduction of shoulder pain following gynaecological laparoscopic procedures; and gasless laparoscopy compared to carbon dioxide insufflation for the reduction of shoulder pain following gynaecological laparoscopic procedures). Two review authors (SA and PK) working independently used GRADE criteria (study limitations (that is, risk of bias), consistency of effect, imprecision, indirectness and publication bias). We resolved disagreements by discussion. Judgements about the quality of the evidence (high, moderate, low

or very low) were justified, documented, and incorporated into the reporting of results for each outcome.

RESULTS

Description of studies

Results of the search

After searching the electronic databases we identified 1465 records, and identified five additional records through other sources, that is, handsearching from systematic reviews. We excluded 474 duplicate records and subsequently excluded a further 996 records. We assessed 82 full-text articles, of which we excluded 43, leaving 35 studies (from 39 records); 3 studies await classification and 32 are included in the qualitative analysis.

For further details on included and excluded studies, see [Characteristics of included studies](#) and [Characteristics of excluded studies](#) tables. The process involved in the screening and selection of eligible studies for inclusion is shown in the PRISMA flow chart (Moher 2009).

Included studies

We included 32 studies (Abbott 2001; Alexander 1987; Benhamou 1994; Chou 2005; Dobbs 1987; Guido 1998; Haghgoo 2016; Herrmann 2015; Johnson 1994; Kafali 2004; Keita 2003; Kim 2014; Kissler 2004; Kocamanoglu 2005; Leelasuwattanakul 2016; Liu 2014; Loughney 1994; Manwaring 2008; Narchi 1991; Ozer 2005; Perry 1993; Phelps 2008; Radosa 2013; Roy 2014; Sharami 2010; Shen 2003; Suginami 2009; Sutthitpongsa 2013; Sutthitpongsa 2015; Swift 2002; Tsai 2011; Tsai 2013).

The following is a summary of the methods, participants, interventions and outcomes of the included studies. Full details of these domains (for each study separately) are in the [Characteristics of included studies](#).

Methods

In total, 32 randomised controlled trials were conducted in 11 countries (Australia, China, France, Germany, India, Iran, Republic of Korea, Taiwan, Turkey, UK and USA). Of these, four were multicentred studies.

Participants

The studies recruited 3284 women in total and included them in the analysis for the incidence/severity of STP post-gynaecological laparoscopy.

Inclusion criteria

Nine studies included an age criterion (Guido 1998; Haghgoo 2016; Keita 2003; Liu 2014; Phelps 2008; Radosa 2013; Sharami 2010; Tsai 2011; Tsai 2013). The lower age range started from 15 years of age (Phelps 2008; Sharami 2010) to 30 years (Radosa 2013). The upper age limits varied from 40 years (Keita 2003) to 70 years (Radosa 2013).

Twelve studies included a criteria regarding American Society of Anesthesiologists (ASA) grading (Keita 2003; Leelasuwattanakul 2016; Liu 2014; Loughney 1994; Ozer 2005; Phelps 2008; Radosa 2013; Sharami 2010; Sutthitpongsa 2013; Sutthitpongsa 2015; Tsai 2011; Tsai 2013). All limiting women to ASA grades of

1-2, except [Leelasuwattanukul 2016](#), who limited inclusion to those women with an ASA grade of 1. Twelve studies included women undergoing only 'minor' gynaecological laparoscopy, that is, diagnostic procedures, laparoscopic sterilisation, etc ([Abbott 2001](#); [Benhamou 1994](#); [Guido 1998](#); [Kafali 2004](#); [Kocamanoglu 2005](#); [Leelasuwattanukul 2016](#); [Liu 2014](#); [Loughney 1994](#); [Narchi 1991](#); [Ozer 2005](#); [Roy 2014](#); [Sharami 2010](#)).

Exclusion criteria

Nine studies had no documented exclusion criteria ([Abbott 2001](#); [Alexander 1987](#); [Kafali 2004](#); [Kissler 2004](#); [Kocamanoglu 2005](#); [Loughney 1994](#); [Suginami 2009](#); [Sutchritpongsa 2015](#); [Tsai 2011](#)). The commonest document exclusion criteria was that of a history of laparotomy in six studies ([Benhamou 1994](#); [Chou 2005](#); [Herrmann 2015](#); [Narchi 1991](#); [Phelps 2008](#); [Sharami 2010](#)) with five studies documenting conversion to laparotomy being a specific exclusion criteria ([Dobbs 1987](#); [Phelps 2008](#); [Radosa 2013](#); [Sharami 2010](#); [Shen 2003](#)).

Only one study used an exclusion criteria specifically associated with haemorrhage. [Radosa 2013](#) excluded women who experienced "major bleeding requiring intra-operative or post-operative transfusion".

Interventions

Five of the 32 studies had three study arms ([Chou 2005](#) ; [Kissler 2004](#); [Kocamanoglu 2005](#); [Radosa 2013](#); [Tsai 2011](#)) with a further three studies having four study arms ([Keita 2003](#); [Kim 2014](#); [Narchi 1991](#)).

Specific technique for releasing the pneumoperitoneum versus 'standard' technique for releasing the pneumoperitoneum

Pulmonary recruitment manoeuvre versus control

Six studies ([Liu 2014](#); [Kim 2014](#); [Phelps 2008](#); [Sharami 2010](#); [Sutchritpongsa 2015](#); [Tsai 2011](#)) investigated manual inflation breaths (pulmonary recruitment manoeuvre). The technique involves positive pressure ventilation at the completion of the laparoscopic procedure whilst the patient is still in a Trendelenburg position. A pressure of between 40 to 60 cm H₂O for five breaths was used with the final inflation breath being held for a maximum of five seconds. The trocar valves were left open to allow carbon dioxide to be expelled from the abdominal cavity. [Phelps 2008](#) and [Tsai 2011](#) used a pressure of 60 cm H₂O, whilst the remaining studies used a lower pressure of 40 cm H₂O because of a concern of the potential for pulmonary injury at the higher pressure. All the studies used the same control, described as gentle abdominal pressure to remove carbon dioxide via open trocars. [Tsai 2011](#) was a three-armed study, with the third arm using normal saline instilled into the upper abdominal cavity (15 to 30 mL/kg body weight) and left inside the abdominal cavity.

Aspiration of carbon dioxide pneumoperitoneum versus control

One study ([Leelasuwattanukul 2016](#)) examined the effect of active aspiration of carbon dioxide from the abdominal cavity following a gynaecological laparoscopy. Whilst the patient was still in a Trendelenburg position, all trocars were opened and an aspiration cannula was placed subdiaphragmatically under direct visualisation, the residual gas was removed by suctioning at 100 mmHg. The control involved the patient remaining in a

Trendelenburg position and gentle abdominal pressure with the trocars opened to allow carbon dioxide to be expelled.

No fluid instillation versus fluid instillation

Three studies investigated the use of intraperitoneal fluid instillation ([Suginami 2009](#); [Tsai 2011](#); [Tsai 2013](#)). [Suginami 2009](#) instilled 1000 to 1500 mL of warm saline into the abdominal cavity at the end of the gynaecological laparoscopy procedure. This was via one of the two supra inguinal ports whilst still in Trendelenburg positioning until it "spilled out of the remaining open trocars". [Tsai 2011](#) was a three-armed study comparing instillation of isotonic normal saline into the upper abdomen at the end of the procedure (15 to 30 mL/kg body weight) versus the use of five manual pulmonary inflation breaths with open trocars versus a control. The control was the clinicians' routine post-procedure process of gentle abdominal pressure with open trocars to aid removal of remaining carbon dioxide.

[Tsai 2013](#) was a two-armed study with the intervention arm including intraperitoneal fluid instillation with five manual pulmonary inflation breaths, as described above versus a control. The amount of fluid instilled was less than in [Tsai 2011](#), being 15 to 30 mL/kg body weight.

Intraperitoneal drain versus no intraperitoneal drain

Five studies investigated the use of an intraperitoneal drain ([Abbott 2001](#); [Alexander 1987](#); [Haghgoo 2016](#); [Shen 2003](#); [Swift 2002](#)). Two studies used patient blinding in the form of a 'dummy drain' ([Abbott 2001](#); [Swift 2002](#)). All studies except for [Shen 2003](#) used passive, that is, non-suction drainage.

Drains remained in-situ for four hours ([Abbott 2001](#); [Swift 2002](#)), for six hours ([Alexander 1987](#)) or for "at least 24 hours" ([Haghgoo 2016](#)). It was unclear from the study report of [Shen 2003](#) when drain removal occurred.

Subdiaphragmatic intraperitoneal local anaesthetic versus no local anaesthetic

Eight studies compared various regimes of intraperitoneal local anaesthetic infiltration to the upper abdomen/subdiaphragmatic area ([Benhamou 1994](#); [Chou 2005](#); [Keita 2003](#); [Kim 2014](#); [Kocamanoglu 2005](#); [Narchi 1991](#); [Ozer 2005](#); [Sutchritpongsa 2013](#)). Three studies had two arms ([Benhamou 1994](#); [Ozer 2005](#); [Sutchritpongsa 2013](#)), two studies had three arms ([Chou 2005](#); [Kocamanoglu 2005](#)) and three studies had four arms ([Keita 2003](#); [Kim 2014](#); [Narchi 1991](#)).

Five studies compared intraperitoneal local anaesthetic with adrenaline versus a control ([Benhamou 1994](#); [Chou 2005](#); [Keita 2003](#); [Narchi 1991](#); [Ozer 2005](#)).

Two studies compared intraperitoneal local anaesthetic with additional opiates (3 mg morphine) versus a control ([Keita 2003](#); [Sutchritpongsa 2013](#)). Two studies compared intraperitoneal local anaesthesia without additional adrenaline or opiates ([Kocamanoglu 2005](#); [Roy 2014](#)).

Seven studies ([Chou 2005](#); [Keita 2003](#); [Kocamanoglu 2005](#); [Narchi 1991](#); [Ozer 2005](#); [Roy 2014](#); [Sutchritpongsa 2013](#)) used bupivacaine (0.125% to 0.5%), two studies ([Benhamou 1994](#); [Narchi 1991](#)) used lignocaine (0.5%) and one study ([Kocamanoglu 2005](#)) used

ropivacaine (0.75%). Full details of the regimes used are in the [Characteristics of included studies](#).

Local anaesthetic to peritoneal cavity (not subdiaphragmatic) versus control

Four studies compared local anaesthetic instillation into the abdominal cavity but not subdiaphragmatic versus a control (Johnson 1994; Loughney 1994; Kim 2014; Roy 2014). All studies used different volumes and strength of local anaesthetic; 10 mL of 0.5% bupivacaine, 10 mL of 0.25% bupivacaine and 17 mL of 0.25% bupivacaine respectively. All studies used normal saline as their controls. Kim 2014 also included in one arm the intervention of a pulmonary recruitment manoeuvre with local anaesthetic instillation into the abdominal cavity, the volume of which was identical to that of the local anaesthetic used in the intervention group. Full details of the regimes used are in the [Characteristics of included studies](#).

Warmed, or warmed and humidified carbon dioxide versus control

Two studies (Herrmann 2015; Manwaring 2008) compared using warmed and humidified carbon dioxide for insufflation during gynaecological laparoscopy versus a control (unwarmed and unhumidified carbon dioxide). The temperature of insufflated gas used in these studies was $35 \pm 2^\circ\text{C}$ and 37°C respectively and the humidity was 98% and 100% respectively. Temperature and humidity was controlled in both studies with the same equipment; HumiGard MR 860 Surgical Humidification System (Fisher & Paykel Healthcare Limited, Auckland, New Zealand).

A third study (Kissler 2004) also investigated the effects of warming and humidifying carbon dioxide during gynaecological laparoscopy. The study however was a three-armed study and used a control group (unwarmed and unhumidified carbon dioxide) and two intervention arms; humidified and heated (38°C) carbon dioxide insufflation gas and dry and heated (38°C) carbon dioxide insufflation gas.

Carbon dioxide insufflation versus the use of gasless laparoscopy

One study investigated the effect of 'gasless' laparoscopy (Guido 1998). The control arm used 'conventional' carbon dioxide laparoscopy for tubal ligation while the intervention arm involved the use of the 'Laprolift' system. This technique physically lifts up the anterior abdominal wall from within the abdominal cavity without the use of a pressured pneumoperitoneum.

Outcomes

Primary outcome

Seventeen studies reported the incidence of STP in their population group (Abbott 2001; Dobbs 1987; Haghgoo 2016; Herrmann 2015; Keita 2003; Kissler 2004; Kocamanoglu 2005; Liu 2014; Loughney 1994; Ozer 2005; Phelps 2008; Roy 2014; Sharami 2010; Shen 2003; Sutthritpongsa 2013; Tsai 2011; Tsai 2013). The time points at which the incidence of STP was noted varied from pre-operatively (baseline incidence) in one study (Abbott 2001), within eight hours (Roy 2014), within 24 hours (Keita 2003; Kocamanoglu 2005), within 48 hours (Herrmann 2015; Liu 2014; Phelps 2008) within 72 hours (Dobbs 1987; Loughney 1994) and up to seven days post-operatively (Ozer 2005). Other studies reported the incidence of STP at highly variable multiple hourly time points; 1, 2, 3, 4, 6, 8, 12, 16, 18, 24, 48, 72, 96 and 120 hours. Three studies assessed for incidence of STP, but these data could not be used in meta-analysis

due to them being a mixture of pain sources and uncertainty in study design (Alexander 1987; Kim 2014; Perry 1993).

Thirty studies reported the severity of STP (Alexander 1987; Benhamou 1994; Chou 2005; Dobbs 1987; Guido 1998; Haghgoo 2016; Herrmann 2015; Johnson 1994; Kafali 2004; Keita 2003; Kim 2014; Kissler 2004; Kocamanoglu 2005; Leelasuwattanakul 2016; Liu 2014; Loughney 1994; Manwaring 2008; Narchi 1991; Ozer 2005; Perry 1993; Phelps 2008; Radosa 2013; Sharami 2010; Shen 2003; Suginami 2009; Sutthritpongsa 2013; Sutthritpongsa 2015; Swift 2002; Tsai 2011; Tsai 2013). The majority of studies utilised a visual analogue scale (VAS) scoring system, most commonly a range of 0 to 10 (Chou 2005; Haghgoo 2016; Kissler 2004; Leelasuwattanakul 2016; Manwaring 2008; Sharami 2010; Swift 2002; Tsai 2011; Tsai 2013). One study used a scale of 0 to 30 (Guido 1998) and one used a scale of 0 to 120 (Johnson 1994). Two studies used Numerical Rating Scales (NRS) (Perry 1993; Radosa 2013). We were unable to use the following sixteen studies in meta-analysis due to the pain being from a mixture of sites, reporting data in an unusable way (e.g. small graphs with no confidence intervals), or not publishing the results (Alexander 1987; Benhamou 1994; Dobbs 1987; Johnson 1994; Keita 2003; Kim 2014; Kissler 2004; Kocamanoglu 2005; Leelasuwattanakul 2016; Liu 2014; Loughney 1994; Ozer 2005; Perry 1993; Suginami 2009; Sutthritpongsa 2013; Sutthritpongsa 2015).

Sixteen studies reported adverse outcomes as their primary or secondary outcomes (Abbott 2001; Benhamou 1994; Guido 1998; Haghgoo 2016; Herrmann 2015; Kocamanoglu 2005; Leelasuwattanakul 2016; Ozer 2005; Phelps 2008; Radosa 2013; Sharami 2010; Shen 2003; Suginami 2009; Sutthritpongsa 2013; Tsai 2011; Tsai 2013). However, only one study (Shen 2003) reported a clinically significant complication that was directly related to the intervention used (infection around drain site requiring antibiotics).

The remaining fifteen studies did not measure adverse outcomes (Alexander 1987; Chou 2005; Dobbs 1987; Johnson 1994; Kafali 2004; Keita 2003; Kim 2014; Kissler 2004; Liu 2014; Loughney 1994; Manwaring 2008; Narchi 1991; Perry 1993; Roy 2014; Swift 2002).

Secondary outcome

Ten studies reported data on analgesia usage post-laparoscopy that we could use in meta-analysis (Benhamou 1994; Chou 2005; Haghgoo 2016; Herrmann 2015; Kafali 2004; Radosa 2013; Sharami 2010; Shen 2003; Tsai 2011; Tsai 2013). A wide range of analgesics were reported from simple oral analgesics, that is, paracetamol (Benhamou 1994; Shen 2003) through to intravenous opiates, that is, pethidine (Tsai 2011). Some studies reported analgesia usage in a way that could not be used in meta-analysis (Johnson 1994; Kissler 2004; Leelasuwattanakul 2016; Liu 2014; Loughney 1994; Manwaring 2008; Ozer 2005; Roy 2014; Sutthritpongsa 2013; Sutthritpongsa 2015).

No studies reported the secondary outcomes of delayed discharge or readmission rates attributable to STP, quality-of-life scores or healthcare costs directly related to STP.

We excluded four of the 32 studies from the meta-analysis as having no usable data (Alexander 1987; Johnson 1994; Kim 2014; Perry 1993).

Excluded studies

We excluded 43 full-text articles that were initially assessed as eligible for inclusion in our review.

- Twenty five studies did not assess for the incidence or severity of shoulder-tip pain, or adverse events ([Arden 2013](#); [Asgari 2017](#); [Beste 2006](#); [Buck 2004](#); [Butala 2013](#); [Ceyhan 2005](#); [Costello 2010](#); [El-Sherbiny 2009](#); [Fagnoni 2003](#); [Gordon 2002](#); [Kayacan 2002](#); [Kelly 1996](#); [Manjunath 2012](#); [Nguyen 2002](#); [Ott 1998](#); [Parsanezhad 2003](#); [Pellicano 1998](#); [Rasooli 2015](#); [Readman 2004](#); [Saleh 2001](#); [Shaw 2001](#); [Somaini 2014](#); [Sripada 2006](#); [Topcu 2014](#); [Wang 2011](#)).
- Seven studies did not have an intervention of interest ([Asgari 2012](#); [Bogani 2014](#); [Gisin 1998](#); [Ikechebelu 2005](#); [Ismail 2013](#); [Jimenez 2014](#); [Madsen 2016](#)).

- Six studies were not RCTs ([Chaichian 2018](#); [Dede 2015](#); [Malhotra 2007](#); [Paech 2008](#); [Raymond 2010](#); [Semm 1994](#)).
- Two studies included women not having a general anaesthetic ([Chakra 2001](#); [Demco 2001](#)).
- One article was a published letter ([Esin 2008](#)).
- One study did not assess the right type of participants, that is, they were general surgical patients ([Khanna 2013](#)).
- One study did not have methods or results available ([Salmanli 1999](#)).

Risk of bias in included studies

A complete overview of classification of 'Risk of bias' domains can be found in the [Characteristics of included studies](#) table, [Figure 2](#) and [Figure 3](#).

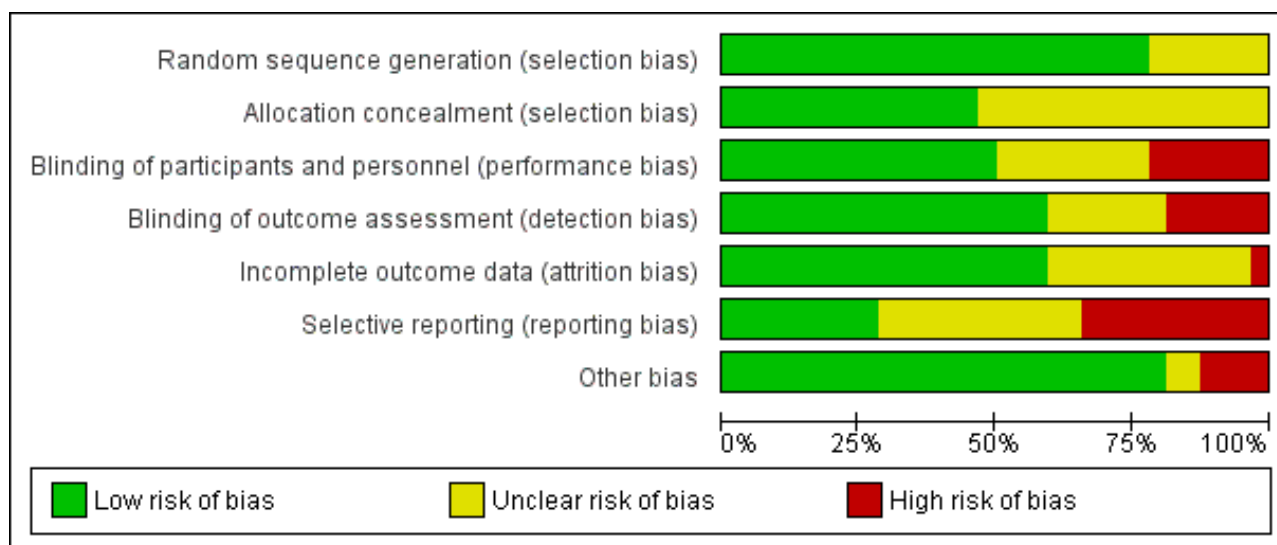
Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Abbott 2001	+	+	+	+	+	+	+
Alexander 1987	?	?	-	-	?	-	+
Benhamou 1994	+	?	?	+	?	?	+
Chou 2005	+	+	+	+	+	-	+
Dobbs 1987	?	?	-	?	-	-	+
Guido 1998	+	+	?	?	?	-	+
Haghgoo 2016	+	?	-	-	+	?	+
Herrmann 2015	+	+	+	+	+	+	+
Johnson 1994	+	+	+	+	+	+	-
Kafali 2004	+	?	?	?	?	?	+
Keita 2003	+	+	?	+	+	?	+
Kim 2014	?	?	?	?	?	?	?
Kissler 2004	+	?	+	+	+	-	-
Kocamanoglu 2005	?	?	?	+	?	?	+
Leelasuwattanakul 2016	+	?	+	+	+	+	+
Liu 2014	+	+	+	+	+	-	+
Loughney 1994	+	?	+	+	?	-	+
Manwaring 2008	+	+	+	+	+	+	+
Narchi 1991	?	?	?	?	+	+	+
Ozer 2005	+	?	+	+	+	?	+

Figure 2. (Continued)

Ozer 2005	+	?	+	+	+	?	+
Perry 1993	+	+	-	-	+	-	+
Phelps 2008	+	+	+	+	+	-	?
Radosa 2013	+	+	+	+	+	+	+
Roy 2014	+	?	+	+	+	?	+
Sharami 2010	+	+	+	+	+	+	-
Shen 2003	+	?	-	-	?	?	+
Suginami 2009	?	?	-	-	?	?	+
Sutthritpongsa 2013	+	?	?	?	?	-	+
Sutthritpongsa 2015	?	?	?	?	?	-	+
Swift 2002	+	+	+	+	?	+	-
Tsai 2011	+	+	-	-	+	?	+
Tsai 2013	+	+	+	+	+	?	+

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



Allocation

Sequence generation

Twenty-five studies were at low risk of random sequence generation, of which 19 studies used computer-generated random numbers for random sequence generation (Abbott 2001; Chou 2005; Guido 1998; Haghighi 2016; Herrmann 2015; Kafali 2004; Kissler 2004; Leelasuwattanakul 2016; Liu 2014; Loughney 1994; Manwaring 2008; Radosa 2013; Roy 2014; Sharami 2010; Shen 2003; Sutthritpongsa 2013; Swift 2002; Tsai 2011; Tsai 2013). Five

studies used random number tables (Benhamou 1994; Johnson 1994; Keita 2003; Ozer 2005; Perry 1993) and one (Phelps 2008) used sealed envelopes, which were manually shuffled and inserted into numbered envelopes.

We did not consider any studies to have a high risk of selection bias because of their random sequence generation.

The remaining seven studies we considered to have an unclear risk for their random sequence generation due to a paucity of

information regarding the methods used (Alexander 1987; Dobbs 1987; Kim 2014; Kocamanoglu 2005; Narchi 1991; Suginami 2009; Sutthritpongsa 2015).

Allocation concealment

Fifteen studies were at low risk of selection bias because of their methods for allocation concealment (Abbott 2001; Chou 2005; Guido 1998; Herrmann 2015; Johnson 1994; Keita 2003; Liu 2014; Manwaring 2008; Perry 1993; Phelps 2008; Radosa 2013; Sharami 2010; Swift 2002; Tsai 2011; Tsai 2013). The main technique for allocation concealment involved the use of sealed opaque envelopes containing the allocation code.

The remaining seventeen studies had an unclear risk of selection bias because their methods for allocation concealment were not described in sufficient detail.

Blinding

Seven studies had a high risk of bias because of the lack of blinding of participants or personnel, or both (Alexander 1987; Dobbs 1987; Haghighi 2016; Perry 1993; Shen 2003; Suginami 2009; Tsai 2011). Three of these studies were likely not to have participant blinding because of the nature of the intervention: Haghighi 2016, presence or absence of a drain; Dobbs 1987, participant would wake up in a tilted position; Suginami 2009, participant may notice more saline spilling from the port sites if in the intervention group. Three studies did not aim to have participant or clinician blinding as part of their study methodology (Alexander 1987; Shen 2003; Tsai 2011).

Sixteen studies had a low risk of bias because they took appropriate measures to blind participants or personnel, or both, to the group allocation (Abbott 2001; Chou 2005; Herrmann 2015; Johnson 1994; Kissler 2004; Leelasuwattanakul 2016; Liu 2014; Loughney 1994; Manwaring 2008; Ozer 2005; Phelps 2008; Radosa 2013; Roy 2014; Sharami 2010; Swift 2002; Tsai 2013).

The remaining nine studies were at an unclear risk of performance bias because the process of blinding was not described in sufficient detail.

Six studies had a high risk of detection bias (Alexander 1987; Haghighi 2016; Perry 1993; Shen 2003; Suginami 2009; Tsai 2011).

Nineteen studies had a low risk of detection bias (Abbott 2001; Benhamou 1994; Chou 2005; Herrmann 2015; Johnson 1994; Keita 2003; Kissler 2004; Kocamanoglu 2005; Leelasuwattanakul 2016; Liu 2014; Loughney 1994; Manwaring 2008; Ozer 2005; Phelps 2008; Radosa 2013; Roy 2014; Sharami 2010; Swift 2002; Tsai 2013).

The remaining seven studies were at unclear risk of detection bias.

Incomplete outcome data

Nineteen studies were at low risk of attrition bias as all dropouts were accounted for and were not considered excessive (Abbott 2001; Chou 2005; Haghighi 2016; Herrmann 2015; Johnson 1994; Keita 2003; Kissler 2004; Leelasuwattanakul 2016; Liu 2014; Manwaring 2008; Narchi 1991; Ozer 2005; Perry 1993; Phelps 2008; Radosa 2013; Roy 2014; Sharami 2010; Tsai 2011; Tsai 2013).

One study was at high risk of attrition bias as the rates were high (Dobbs 1987). The remaining twelve studies were at unclear risk of

attrition bias because the reasons for attrition were not described in sufficient detail.

Selective reporting

Eleven studies had a high risk of reporting bias because of selective reporting (Alexander 1987; Chou 2005; Dobbs 1987; Guido 1998; Kissler 2004; Liu 2014; Loughney 1994; Perry 1993; Phelps 2008; Sutthritpongsa 2013; Sutthritpongsa 2015). These studies did not report on one or more outcomes that were pre-defined in their methodology. Liu 2014 reported on left and right STP in their results section with no comment regarding this outcome in their methods section and therefore we also considered this study to be at high risk of selective reporting bias.

Nine studies had a low risk of selective reporting bias (Abbott 2001; Herrmann 2015; Johnson 1994; Leelasuwattanakul 2016; Manwaring 2008; Narchi 1991; Radosa 2013; Sharami 2010; Swift 2002). All outcomes were either reported in the published studies or were made available as unpublished data (Herrmann 2015).

Twelve studies were at an unclear risk of selective reporting because of a lack of sufficient detail in the method section of their studies.

Other potential sources of bias

Four studies had additional sources of bias (Johnson 1994; Kissler 2004; Sharami 2010; Swift 2002). The most frequent risk of other bias was from significant imbalances in the operative details of the control and intervention group (Johnson 1994; Sharami 2010; Swift 2002). For example, the latter study had seven laparoscopic hysterectomies in the control group and none in the intervention group; the increasing complexity, duration and blood loss associated with hysterectomies potentially being a source of bias.

Other potential sources of bias were Phelps 2008 including a participant undergoing an umbilical hernia repair, Kissler 2004 deviating from study protocol with some randomised women not receiving intended interventions and Sutthritpongsa 2013 using non-standardised pre-operative and intra-operative analgesia regimes throughout their study.

Effects of interventions

See: **Summary of findings for the main comparison** Specific technique compared to standard technique for releasing the pneumoperitoneum for the reduction of shoulder pain following gynaecological laparoscopic procedures; **Summary of findings 2** Fluid instillation compared to no fluid instillation for the reduction of shoulder pain following gynaecological laparoscopic procedures; **Summary of findings 3** Intraperitoneal drain compared to no intraperitoneal drain for the reduction of shoulder pain following gynaecological laparoscopic procedures; **Summary of findings 4** Subdiaphragmatic intraperitoneal local anaesthetic compared to control for the reduction of shoulder pain following gynaecological laparoscopic procedures; **Summary of findings 5** Local anaesthetic to peritoneal cavity (not subdiaphragmatic) compared to control for the reduction of shoulder pain following gynaecological laparoscopic procedures; **Summary of findings 6** Warmed, or warmed and humidified CO₂ compared to unwarmed and unhumidified CO₂ for the reduction of shoulder pain following gynaecological laparoscopic procedures; **Summary of findings 7**

Gasless laparoscopy compared to CO₂ insufflation for the reduction of shoulder pain following gynaecological laparoscopic procedures**1. Specific technique for releasing the pneumoperitoneum versus 'standard' technique for releasing the pneumoperitoneum**

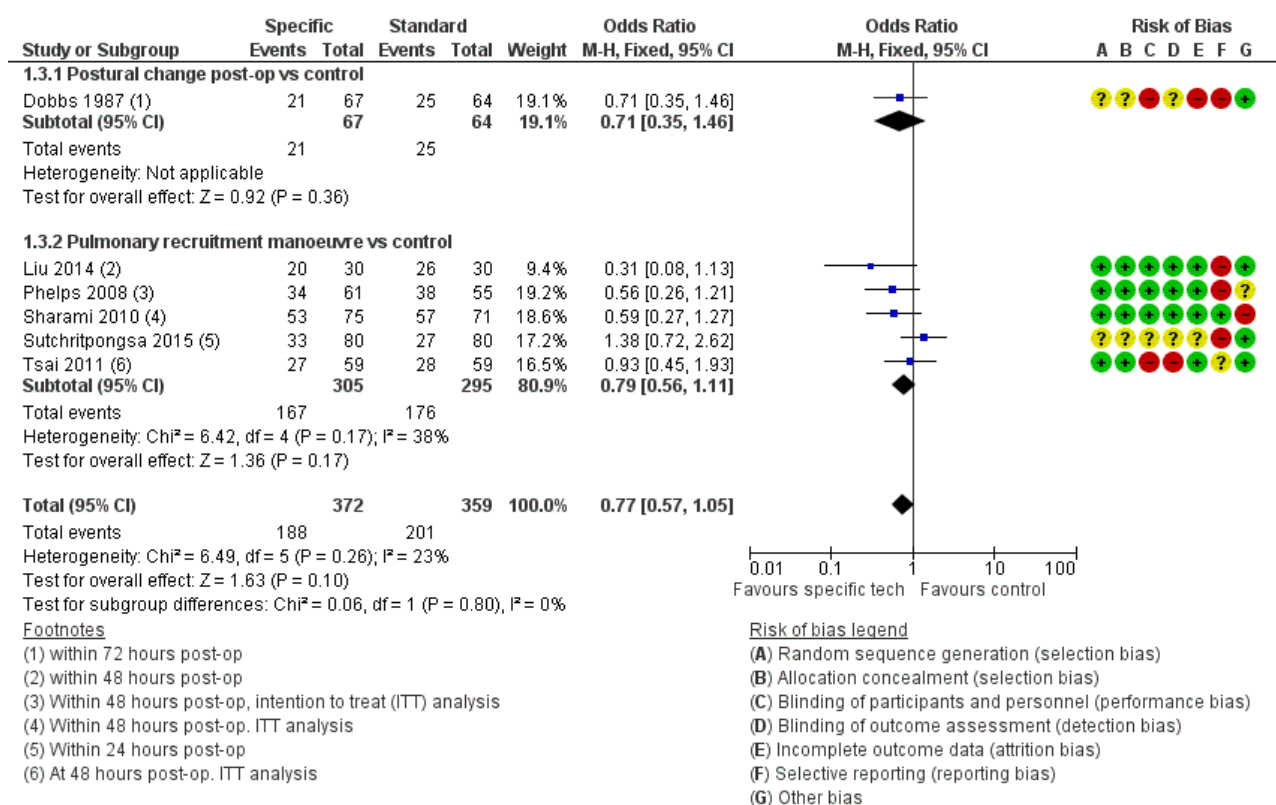
Nine included studies examined this comparison. The 'specific techniques' utilised as interventions differed between studies. Five studies used the pulmonary recruitment manoeuvre (PRM) as the intervention (Dobbs 1987; Phelps 2008; Sharami 2010; Sutthritpongsa 2015; Tsai 2011). Radosa 2013 used 'extended assisted ventilation' (EAV) as one intervention arm and 'extended assisted ventilation with trocar site infiltration of local anaesthetic' (EAV & TSI) as the other. Dobbs 1987 utilised a post-operative postural change for the participants in the intervention arm. Finally, Kafali 2004 and Leelasuwattanakul 2016 used 'active intraperitoneal gas aspiration' as the intervention. Due to the number of studies that assessed the PRM, we were unable to subgroup these studies.

Primary outcomes**1.1 Incidence of STP**

Six included studies assessed the incidence of STP at different time intervals post-operatively; Dobbs 1987; Liu 2014; Phelps 2008; Sharami 2010; Sutthritpongsa 2015; Tsai 2011.

We have pooled the results of all studies within the outcome 'incidence of STP within 72 hours post-operatively' and performed ITT analysis. Four studies examined incidence at 48 hours post-operatively (Liu 2014; Phelps 2008; Sharami 2010; Tsai 2011), one at 72 hours (Dobbs 1987) and one within 24 hours (Sutthritpongsa 2015). The pooled result indicates that there is no evidence of a difference in the incidence of STP when using a specific technique for releasing the pneumoperitoneum versus a standard one (OR 0.77, 95% CI 0.57 to 1.05; 6 RCTs; 731 participants; $I^2 = 23\%$; low-quality evidence; Analysis 1.3; Figure 4). Five out of six of these studies used the PRM as the intervention. Subgrouping results for this specific intervention still reveals no evidence of a difference in incidence of STP between PRM and control (OR 0.79, 95% CI 0.56 to 1.11; 5 RCTs; 600 participants; $I^2 = 38\%$; low-quality evidence; Analysis 1.3).

Figure 4. Forest plot of comparison 1. Standard versus specific technique for releasing the pneumoperitoneum, outcome: 1.3 Incidence of shoulder tip pain within 72 hours post op.



Tsai 2011 also assessed incidence of STP at 12 and 24 hours post-operatively. There is low-quality evidence of little or no difference in the incidence of STP between a specific technique (in this case the PRM) versus standard technique for releasing the pneumoperitoneum at 12 hours (OR 1.23, 95% CI 0.59 to 2.53; 1 RCT; 118 participants; low-quality evidence; Analysis 1.1) and 24 hours

(OR 0.87, 95% CI 0.41 to 1.82; 1 RCT; 118 participants; low-quality evidence; Analysis 1.2).

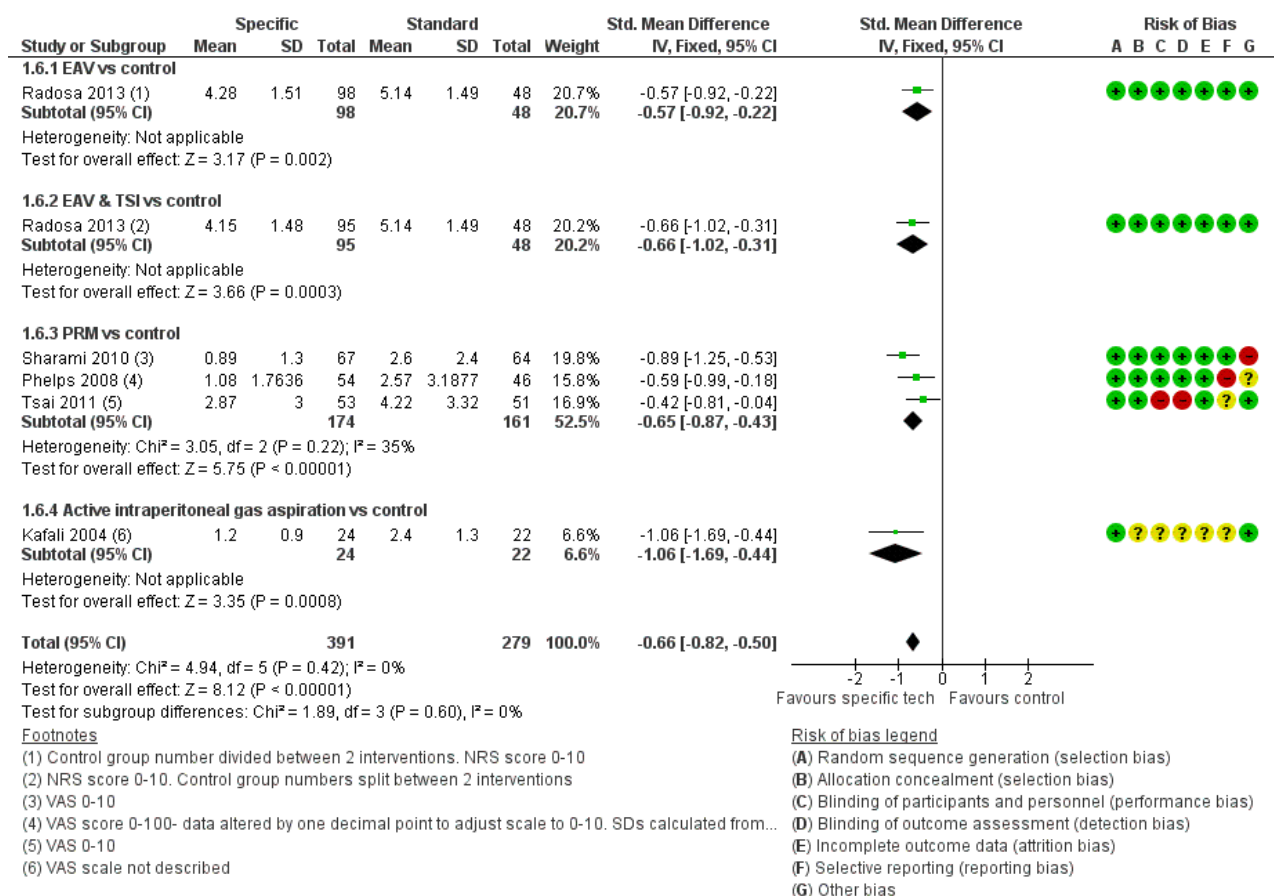
1.2 Severity of STP

Five included studies assessed this outcome at various time points post-operatively. All studies used a VAS score 0 to 10 except for

Phelps 2008, who used 0 to 100 and Kafali 2004, who did not describe the scale used. We altered data from Phelps 2008 by one decimal point to match the VAS scale used by the other studies. In addition, we converted standard errors (SEs) to standard deviations (SDs) and utilised standardised mean differences (SMDs) in comparisons including Kafali 2004, as the length of the scale was uncertain.

We were able to pool the results on severity of STP from all five studies at 24 hours post-operatively. The result reveals that there is low-quality evidence of an association between utilising a specific technique to release the pneumoperitoneum and a reduction in the severity of STP experienced when compared with a standard technique (SMD -0.66, 95% CI -0.82 to -0.50; 5 RCTs; 670 participants; $I^2 = 0\%$; low-quality evidence; Analysis 1.6; Figure 5). This association is also found at the other time points assessed:

Figure 5. Forest plot of comparison 1. Standard versus specific technique for releasing the pneumoperitoneum, outcome: 1.6 Severity of postoperative shoulder tip pain at 24 hours.



- three to six hours post-operatively (SMD -0.29, 95% CI -0.48 to -0.09; 3 RCTs; 466 participants; $I^2 = 87\%$; low-quality evidence; Analysis 1.4);
- 12 hours post-operatively (SMD -0.58, 95% CI -0.78 to -0.37; 4 RCTs; 381 participants; $I^2 = 61\%$; very low-quality evidence; Analysis 1.5);
- 36 hours post-operatively (MD -1.26, 95% CI -2.23 to -0.29; 1 RCT; 100 participants; low-quality evidence; Analysis 1.7);
- 48 hours post-operatively (MD -0.72, 95% CI -0.99 to -0.45; 3 RCTs; 524 participants; $I^2 = 24\%$; very low-quality evidence; Analysis 1.8).

Three of the five studies utilised PRM as the intervention and all assessed severity of STP at 12 and 24 hours post-operatively. When these studies are subgrouped, the pooled result still reveals very low-quality evidence of an association between PRM and a

reduction in the severity of STP when compared to no PRM at 12 hours (SMD -0.57, 95% CI -0.79 to -0.35; $I^2 = 74\%$) and 24 hours (SMD -0.65 95% CI -0.87 to -0.43 3 RCTs, 335 participants; $I^2 = 35\%$; very low-quality evidence).

1.3 Adverse events directly attributable to the intervention

One small, low-risk-of-bias study assessed this outcome (Leelasuwattanakul 2016). No adverse events occurred in either arm of the study, therefore the result is not estimable; Analysis 1.9.

Secondary outcomes

1.4 Analgesia usage

Four studies assessed this outcome. Each study used a different analgesic drug. Radosa 2013 used piritramide, Sharami 2010 used diclofenac, Tsai 2011 used meperidine and Kafali 2004 used tramadol. We pooled the result of each analgesic drug

in milligrams. The low-quality evidence revealed an association between a specific technique for releasing the pneumoperitoneum and a reduction in analgesia usage compared with the standard technique for releasing the pneumoperitoneum (SMD -0.53, 95% CI -0.70 to -0.35; 4 RCTs; 570 participants; $I^2 = 91\%$; low-quality evidence; [Analysis 1.10](#)).

1.5 Delay in discharge

None of the included studies assessed this outcome.

1.6 Readmission rates

None of the included studies assessed this outcome.

1.7 Quality-of-life scores

None of the included studies assessed this outcome.

1.8 Directly related healthcare costs

None of the included studies assessed this outcome.

2. Fluid instillation versus no fluid instillation

Three included studies assessed this comparison ([Perry 1993](#); [Tsai 2011](#); [Tsai 2013](#)). We were unable to use data from [Perry 1993](#) for

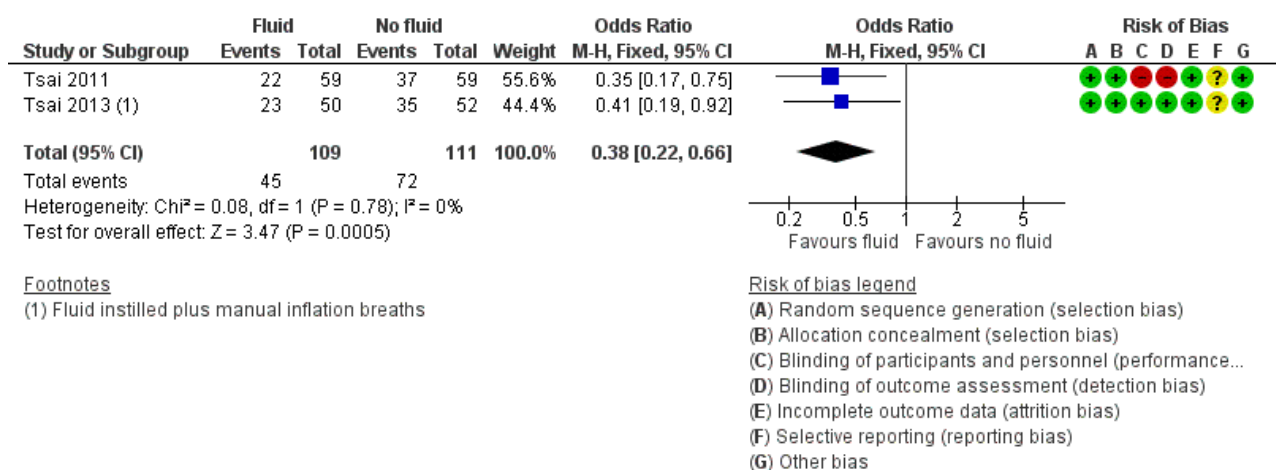
meta-analysis because the severity of STP data were mixed with neck pain and the incidence of STP data were presented in relation to posture, which was not an outcome we were interested in. [Tsai 2011](#) had two intervention arms, only one of which concerns fluid instillation, data from which has been used here. The two studies by Tsai were conducted by the same team of researchers in Taiwan. Both studies assessed the administration of isotonic normal saline at 15 to 30 mL/kg body weight to the upper part of the abdominal cavity. [Tsai 2013](#) also performed five manual pulmonary inflation breaths at 60 cm H₂O. The control groups did not receive any fluid.

Primary outcomes

2.1 Incidence of STP

[Tsai 2011](#) and [Tsai 2013](#), with a total of 220 participants, assessed this outcome at 12, 24 and 48 hours post-operatively. There is moderate-quality evidence that suggests that fluid instillation is probably associated with a reduction in the incidence of STP post-operatively compared with no fluid instillation at 12 hours (OR 0.67, 95% CI 0.39 to 1.14; $I^2 = 0\%$; [Analysis 2.1](#)), 24 hours (OR 0.38, 95% CI 0.22 to 0.66; $I^2 = 0\%$; [Analysis 2.2](#)) and 48 hours (OR 0.38, 95% CI 0.21 to 0.67; $I^2 = 0\%$; [Analysis 2.3](#); [Figure 6](#)).

Figure 6. Forest plot of comparison: 2 Fluid instillation versus no fluid instillation, outcome: 2.2 Incidence of shoulder tip pain at 24 hours post-op.



2.2 Severity of STP

[Tsai 2011](#) and [Tsai 2013](#) reported this outcome for a total of 205 participants at 12, 24 and 48 hours post-operatively using a VAS 0 to 10 cm. There is moderate-quality evidence that suggests that fluid instillation is probably associated with a reduction in the severity of STP compared with no fluid instillation at 12 hours (MD -1.69, 95% CI -2.55 to -0.83; $I^2 = 0\%$; [Analysis 2.4](#)), 24 hours (MD -2.27, 95% CI -3.06 to -1.48; $I^2 = 29\%$; [Analysis 2.5](#)), and 48 hours (MD -1.44, 95% CI -2.07 to -0.81; $I^2 = 0\%$; [Analysis 2.6](#)).

2.3 Adverse events directly attributable to the intervention

None of the included studies assessed this outcome.

Secondary outcomes

2.4 Analgesia usage

[Tsai 2011](#) and [Tsai 2013](#) assessed this outcome using meperidine as the common analgesic over a 24-hour post-operative period. There is low-quality evidence that suggests that fluid instillation may be associated with a reduction in the use of post-operative analgesia for STP when compared with no fluid instillation (MD -12.02, 95% CI -23.97 to -0.06; 2 RCTs; 205 participants; $I^2 = 0\%$; low-quality evidence; [Analysis 2.7](#)).

2.5 Delay in discharge

None of the included studies assessed this outcome.

2.6 Readmission rates

None of the included studies assessed this outcome.

2.7 Quality-of-life scores

None of the included studies assessed this outcome.

2.8 Directly related healthcare costs

None of the included studies assessed this outcome.

3. Intraperitoneal drain versus no intraperitoneal drain

Five included studies assessed this comparison (Abbott 2001; Alexander 1987; Haghgoo 2016; Shen 2003; Swift 2002), however we were unable to extract any data from Alexander 1987 owing to the fact that incidence and severity of STP were combined with chest and abdominal pain data. We could not contact any trial authors for further data.

Primary outcomes

3.1 Incidence of STP

Three studies assessed this outcome at various time points post-operatively (Abbott 2001; Haghgoo 2016; Shen 2003). All three studies utilised a non-suction drain as the intervention, which was left in situ for between four (Abbott 2001) and 24 hours (Haghgoo 2016). It is unknown how long the drain remained in situ in the study by Shen 2003. Abbott 2001 utilised a dummy drain as the control but neither Haghgoo 2016 nor Shen 2003 utilised a 'dummy' drain.

Moderate- to low-quality evidence suggests that there may be association between an intraperitoneal drain and a reduction in the incidence of STP when compared with no intraperitoneal drain at all time points assessed post-operatively:

- three to four hours post-operatively, OR 0.47 (95% CI 0.25 to 0.86; 2 RCTs; 325 participants; $I^2 = 0\%$; low-quality evidence; Analysis 3.1);
- 12 hours post-operatively, OR 0.08 (95% CI 0.02 to 0.36; 1 RCT; 92 participants; low-quality evidence; Analysis 3.2);
- 24 hours post-operatively, OR 0.30 (95% CI 0.20 to 0.46; 3 RCTs; 417 participants; $I^2 = 90\%$; low-quality evidence; Analysis 3.3.
- 48 hours post-operatively, OR 0.40 (95% CI 0.21 to 0.74; 3 RCTs; 417 participants; $I^2 = 0\%$; moderate-quality evidence; Analysis 3.4).

3.2 Severity of STP

Three studies assessed this outcome at various time points post-operatively (Haghgoo 2016; Shen 2003; Swift 2002). Swift 2002 was the only study that was able to blind their control participants with a blocked 'dummy' drain. The time that the drains remained in situ varied from four hours with Swift 2002, to 24 hours with Haghgoo 2016. It is unknown how long the drain remained in situ in Shen 2003.

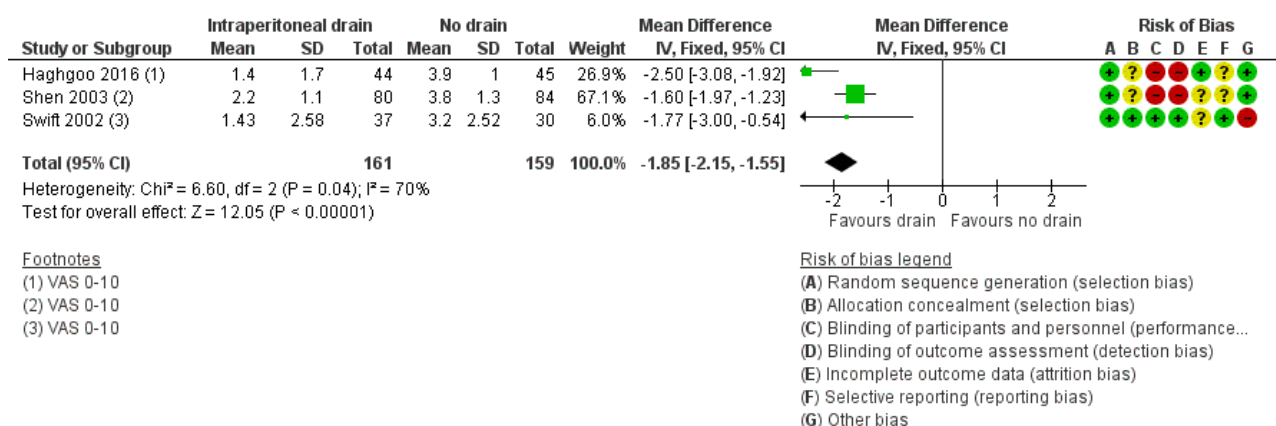
There is conflicting evidence on the impact of an intraperitoneal drain on severity of post-operative STP. At three to four hours and five to six days post-operatively there is no evidence of a difference in severity of STP in women randomised to receive an intraperitoneal drain and those randomised to receive no drain or a dummy drain (low-quality evidence):

- three to four hours post-operatively, MD -0.10 (95% CI -0.29 to 0.10; 2 RCTs; 231 participants; $I^2 = 0\%$; low-quality evidence; Analysis 3.5);
- 96 hours post-operatively, MD -0.54 (95% CI -1.20 to 0.12; 1 RCT; 67 participants; low-quality evidence; Analysis 3.10);
- 120 hours post-operatively, MD -0.13 (95% CI -0.55 to 0.29; 1 RCT; 67 participants; low-quality evidence; Analysis 3.11);

However, at 12, 24, 48 and 72 hours post-operatively, the evidence suggests that an intraperitoneal drain is associated with a reduction in the severity of STP compared to no drain/dummy drain. However this finding is uncertain due to the very low quality of most of the evidence:

- 12 hours post-operatively, MD -1.69 (95% CI -2.2 to -1.19; 2 RCTs; 156 participants; $I^2 = 0\%$; low-quality evidence; Analysis 3.6);
- 24 hours post-operatively, MD -1.85 (95% CI -2.15 to -1.55; 3 RCTs; 320 participants; $I^2 = 70\%$; very low-quality evidence; Analysis 3.7; Figure 7);
- 48 hours post-operatively, MD -0.70 (95% CI -0.95 to -0.44; 3 RCTs; 320 participants; $I^2 = 82\%$; very low-quality evidence; Analysis 3.8);
- 72 hours post-operatively, MD -0.80 (95% CI -1.55 to -0.05; 1 RCT; 67 participants; low-quality evidence; Analysis 3.9).

Figure 7. Forest plot of comparison: 3 Intraperitoneal drain versus no drain, outcome: 3.7 Severity of shoulder tip pain at 24 hours.



3.3 Adverse events directly attributable to the intervention

None of the included studies assessed this outcome.

Secondary outcomes

3.4 Analgesia usage

Two studies assessed this outcome. [Haghgoo 2016](#) assessed mean number of 100 mg diclofenac tablets administered to participants for STP over a 48-hour period post-operatively and [Shen 2003](#) assessed the mean number of 500 mg paracetamol tablets administered over a 48-hour period. We combined the two studies in meta-analysis using a standardised mean difference.

The evidence suggests that an intraperitoneal drain may reduce the amount of analgesia required when compared with no intraperitoneal drain (SMD -1.84, 95% CI -2.14 to -1.54; 2 RCTs; 253 participants; $I^2 = 90\%$; low-quality evidence; [Analysis 3.12](#)).

3.5 Delay in discharge

None of the included studies assessed this outcome.

3.6 Readmission rates

None of the included studies assessed this outcome.

3.7 Quality-of-life scores

None of the included studies assessed this outcome.

3.8 Directly related healthcare costs

None of the included studies assessed this outcome.

4. Subdiaphragmatic intraperitoneal local anaesthetic versus control

Seven included studies assessed this comparison ([Benhamou 1994](#); [Chou 2005](#); [Keita 2003](#); [Kocamanoglu 2005](#); [Narchi 1991](#); [Ozer 2005](#); [Sutthritpongsa 2013](#)). Four studies had more than one intervention arm, hence we split the participant numbers of the control groups of these studies between the various interventions in order to not artificially inflate the weight of the control data.

The local anaesthetic doses and volumes used as the intervention were diverse. All studies apart from [Benhamou 1994](#) utilised bupivacaine as an intervention; some with epinephrine ([Chou 2005](#); [Keita 2003](#); [Narchi 1991](#); [Ozer 2005](#)), and some in combination with 3 mg morphine ([Keita 2003](#); [Sutthritpongsa 2013](#)). The concentration varies from 0.125% to 0.5% and the volumes vary between 20 mL and 80 mL. [Benhamou 1994](#) and an intervention arm of [Narchi 1991](#) utilised 80 mL 0.5% lidocaine with adrenaline as their intervention. [Kocamanoglu 2005](#) utilised 20 mL 0.75% ropivacaine and [Keita 2003](#) utilised 3 mg morphine mixed with 20 mL saline.

Likewise, the control groups were diverse; [Kocamanoglu 2005](#) and [Narchi 1991](#) had no fluid instillation as their control. [Benhamou 1994](#); [Keita 2003](#); [Ozer 2005](#) and [Sutthritpongsa 2013](#) used 0.9% saline as their control. [Chou 2005](#) utilised Ringer's lactate as a control fluid.

We were not able to subgroup studies according to type and volume of local anaesthetic in light of too few studies comparing similar interventions.

Primary outcomes

4.1 Incidence of STP

Four studies assessed this outcome ([Keita 2003](#); [Kocamanoglu 2005](#); [Ozer 2005](#); [Sutthritpongsa 2013](#)). The evidence indicated that there is probably little or no difference in the incidence of STP post-operatively between women receiving subdiaphragmatic intraperitoneal local anaesthetic versus control (OR 0.72, 95% CI 0.42 to 1.23; 4 RCTs; 336 participants; $I^2 = 0\%$; moderate-quality evidence; [Analysis 4.1](#)).

4.2 Severity of STP

Two studies with two intervention arms each studied this outcome at various time points post-operatively ([Chou 2005](#); [Narchi 1991](#)). [Chou 2005](#) had one intervention arm of women receiving 40 mL Ringer's lactate with 10 mL 0.5% bupivacaine with epinephrine after the procedure and the other arm received the same before and after the procedure. [Narchi 1991](#) had one intervention arm of 80 mL 0.5% lidocaine with epinephrine and one of 80 mL 0.125% bupivacaine with epinephrine.

At 2, 4, 8, 12 to 16, 24, 36 and 48 hours post-operatively, the evidence suggested that there may be no difference between the groups in the severity of STP:

- two hours post-operatively, MD -0.23 (95% CI -0.71 to 0.25; 2 RCTs; 129 participants; $I^2 = 0\%$; moderate-quality evidence; [Analysis 4.2](#));
- 4 hours post-operatively, MD -1.05 (95% CI -2.17 to 0.06; 1 RCT; 79 participants; low-quality evidence; [Analysis 4.3](#));
- 12 to 16 hours post-operatively, MD -1.08 (95% CI -2.18 to -0.03; 1 RCT; 79 participants; low-quality evidence; [Analysis 4.5](#));
- 24 hours post-operatively, MD -1.13 (95% CI -2.52 to 0.26; 1 RCT; 50 participants; low-quality evidence; [Analysis 4.6](#));
- 36 hours post-operatively, MD -1.64, 95% CI -3.36 to 0.09; 1 RCT; 50 participants; low-quality evidence; [Analysis 4.7](#));
- 48 hours post-operatively, MD -1.00, 95% CI -2.06 to 0.06; 1 RCT; 50 participants; low-quality evidence; [Analysis 4.8](#));

At eight hours post-operatively, the evidence suggests that subdiaphragmatic intraperitoneal local anaesthetic is associated with a reduction in the severity of STP (MD -0.95, 95% CI -1.70 to -0.19; 2 RCTs; 129 participants; $I^2 = 38\%$; moderate-quality evidence; [Analysis 4.4](#)).

4.3 Adverse events directly attributable to the intervention

Three studies assessed this outcome ([Benhamou 1994](#); [Kocamanoglu 2005](#); [Narchi 1991](#)). There were no adverse events noted in any arm of these studies, therefore the result was not estimable (3 RCTs; 165 participants; low-quality evidence; [Analysis 4.9](#)).

Secondary outcomes

4.4 Analgesia usage

Two studies assessed this outcome. [Benhamou 1994](#) examined mean number of 500 mg paracetamol tablets taken for STP relief within a 48-hour period post-operatively. [Chou 2005](#) examined mean meperidine consumption for STP relief within 24 hours post-operatively. We combined these studies in meta-analysis using a standardised mean difference.

The evidence suggests an association between subdiaphragmatic intraperitoneal local anaesthetic and lower analgesia usage (SMD -0.57, 95% CI -0.94 to -0.21; 2 RCTs; 129 participants; $I^2 = 51\%$; low-quality evidence; [Analysis 4.10](#)).

4.5 Delay in discharge

None of the included studies assessed this outcome.

4.6 Readmission rates

None of the included studies assessed this outcome.

4.7 Quality-of-life scores

None of the included studies assessed this outcome.

4.8 Directly related healthcare costs

None of the included studies assessed this outcome.

5. Local anaesthetic to peritoneal cavity (not subdiaphragmatic) versus control

Three included studies assessed this comparison ([Johnson 1994](#); [Loughney 1994](#); [Roy 2014](#)), however we were unable to extract any data from [Johnson 1994](#) owing to it being published in graph format. We contacted the lead author who did not have the original study data easily available to share because it was in very old digital format. The paper-based study data were destroyed many years ago.

[Loughney 1994](#) and [Roy 2014](#) both utilised 0.25% bupivacaine as the intervention, but in different volumes; 17 mL and 10 mL respectively. The control in both groups was normal saline; 17 mL and 10 mL respectively. Both studies describe instillation of local anaesthetic to the peritoneal cavity at the end of the operation.

Primary outcomes

5.1 Incidence of STP

Both studies assessed this outcome. [Loughney 1994](#) assessed incidence within four hours post-operatively and [Roy 2014](#) assessed within eight hours post-operatively.

The evidence suggested that local anaesthetic to the peritoneal cavity (not subdiaphragmatic) may be associated with a reduction in the incidence of STP post-operatively (OR 0.23, 95% CI 0.06 to 0.93; 2 RCTs; 157 participants; $I^2 = 56\%$; low-quality evidence; [Analysis 5.1](#)). The different volumes of local anaesthetic administered in these studies should be noted.

5.2 Severity of STP

This outcome was not assessed by any studies.

5.3 Adverse events directly attributable to the intervention

None of the included studies assessed this outcome.

Secondary outcomes

5.4 Analgesia usage

None of the included studies assessed this outcome.

5.5 Delay in discharge

None of the included studies assessed this outcome.

5.6 Readmission rates

None of the included studies assessed this outcome.

5.7 Quality-of-life scores

None of the included studies assessed this outcome.

5.8 Directly related healthcare costs

None of the included studies assessed this outcome.

6 Warmed, or warmed and humidified insufflating gas versus unwarmed and unhumidified insufflating gas

Three included studies assessed this comparison. [Herrmann 2015](#) and [Manwaring 2008](#) utilised warmed and humidified carbon dioxide as the intervention. [Kissler 2004](#) had two intervention arms; one with warmed and humidified carbon dioxide and the other with warmed and unhumidified carbon dioxide. We divided the control group participant numbers between the two intervention arms for the purposes of this review.

Primary outcomes

6.1 Incidence of STP

Two studies assessed this outcome; [Herrmann 2015](#) and [Kissler 2004](#).

The evidence suggests that there may be no difference in the incidence of STP post-operatively when warmed, or warmed and humidified carbon dioxide is used versus unwarmed and unhumidified carbon dioxide (OR 0.81, 95% CI 0.45 to 1.49; 2 RCTs; 194 participants; $I^2 = 12\%$; low-quality evidence; [Analysis 6.1](#)). We performed a subgroup analysis of women who received warmed and humidified gas as the intervention, and again, the data revealed no evidence of a difference in the incidence of STP post-operatively (OR 0.78, 95% CI 0.40 to 1.52; 2 RCTs; 149 participants; $I^2 = 54\%$; very low-quality evidence).

6.2 Severity of STP

Two studies assessed this outcome at 2, 4 and 24 hours post-operatively ([Herrmann 2015](#); [Manwaring 2008](#)). There was evidence that there was probably no difference in the severity of STP experienced when warmed and humidified carbon dioxide was used versus unwarmed and unhumidified carbon dioxide, at any of these time points: two hours post-operatively (MD -0.19, 95% CI -0.61 to 0.23; $I^2 = 64\%$; moderate-quality evidence; [Analysis 6.3](#)); four hours post-operatively (MD 0.05, 95% CI -0.26 to 0.36; $I^2 = 0\%$; high-quality evidence; [Analysis 6.4](#)); and 24 hours post-operatively (MD 0.11, 95% CI -0.75 to 0.97; 2 RCTs; 155 participants; $I^2 = 50\%$; moderate-quality evidence; [Analysis 6.5](#)).

[Manwaring 2008](#) assessed the severity of STP at one hour post-operatively and [Herrmann 2015](#) at 48 hours post-operatively. There was no evidence of a difference in the severity of STP experienced when warmed and humidified carbon dioxide was used versus unwarmed and unhumidified carbon dioxide at either time point: one hour post-operatively (MD 0.00 95% CI -0.76 to 0.76; 1 RCT; 60 participants; moderate-quality evidence; [Analysis 6.2](#)); and 48 hours post-operatively (MD -0.39, 95% CI -1.36 to 0.58; 1 RCT; 96 participants; moderate-quality evidence; [Analysis 6.6](#)).

6.3 Adverse events directly attributable to the intervention

None of the included studies assessed this outcome.

Secondary outcomes

6.4 Analgesia usage

One study assessed this outcome ([Herrmann 2015](#)) and reported morphine use in milligrams over a 48-hour period post-operatively. There was evidence that there may be no difference in the usage of analgesia when warmed and humidified carbon dioxide is used versus unwarmed and unhumidified carbon dioxide (MD -4.97, 95% CI -11.25 to 1.31; 1 RCT; 95 participants; low-quality evidence; [Analysis 6.7](#)).

6.5 Delay in discharge

None of the included studies assessed this outcome.

6.6 Readmission rates

None of the included studies assessed this outcome.

6.7 Quality-of-life scores

None of the included studies assessed this outcome.

6.8 Directly related healthcare costs

None of the included studies assessed this outcome.

7. Gasless laparoscopy versus carbon dioxide insufflation

Only one study ([Guido 1998](#)) assessed this comparison.

Primary outcomes

7.1 Incidence of STP

None of the included studies assessed this outcome.

7.2 Severity of STP

[Guido 1998](#) used a VAS of 0 to 30 for this outcome. They published the mean pain scores, along with 95% CIs, over a 72-hour period, from which we calculated standard deviations. The evidence suggests that gasless laparoscopy may be associated with increased severity of STP, compared with carbon dioxide insufflation (MD 3.80, 95% CI 0.76 to 6.84; 1 RCT; 54 participants; low-quality evidence; [Analysis 7.1](#))

7.3 Adverse events directly attributable to the intervention

Of the 24 women randomised to the conventional carbon dioxide laparoscopy group, one underwent a laparotomy for internal iliac laceration with the Veress needle and one suffered a uterine perforation during placement of the uterine manipulator. Of the 30 women randomised to the gasless laparoscopy group, one underwent a laparotomy for bleeding from the fallopian tube, one developed an omental haematoma as a direct result of entrapment while placing the Laprofan and one suffered a uterine perforation during placement of uterine manipulator. Only the omental haematoma could be related to the use of the Laprofan and was considered to be clinically insignificant. We were unable to undertake an ITT analysis of these data as we could not determine the number of women who were randomised to each group before dropouts.

Likewise, there was too little evidence to determine whether there was a difference in adverse events between conventional carbon dioxide laparoscopy when compared with gasless laparoscopy (OR 2.56, 95% CI 0.25 to 26.28; 1 RCT; 54 participants; very low-quality evidence; [Analysis 7.2](#)).

Secondary outcomes

7.4 Analgesia usage

None of the included studies assessed this outcome.

7.5 Delay in discharge

None of the included studies assessed this outcome.

7.6 Readmission rates

None of the included studies assessed this outcome.

7.7 Quality-of-life scores

None of the included studies assessed this outcome.

7.8 Directly related healthcare costs

None of the included studies assessed this outcome.

8. Alternative insufflating gas versus carbon dioxide insufflation

We did not find any studies that assessed this comparison.

Subgroup analyses

We did not undertake subgroup analysis as planned for the extent of surgery (minor or major) because many studies included a combination of minor and major procedures. Also, some studies did not describe the extent of gynaecological surgery, making them impossible to subgroup.

We undertook subgroup analysis for some of the interventions outlined under the comparison 'specific technique for releasing the pneumoperitoneum'. In [Analysis 1.3](#); [Analysis 1.5](#); [Analysis 1.6](#) and [Analysis 1.8](#), we subgrouped the studies undertaking PRM versus control. We have described these results above.

We also undertook subgroup analysis for women who underwent laparoscopy with warmed and humidified gas versus control under [Analysis 6.1](#). We have described the results under the comparison 'warmed, or warmed and humidified insufflating gas versus unwarmed and unhumidified insufflating gas'.

Sensitivity analysis

We did not undertake a sensitivity analysis restricted to studies with only low risk of bias, because many included studies had one domain at high risk of bias, and many had 'unknown' risks of bias over a number of domains.

We undertook a sensitivity analysis by applying the random-effects model to our primary outcomes to see if the result would change, leading to a change in our conclusions. In three analyses, the overall finding changed with the random-effects model: [Analysis 1.4](#); [Analysis 1.8](#); and [Analysis 5.1](#). The findings altered from showing evidence of an improvement in incidence and severity of STP with the intervention, to showing no evidence of a difference when the random-effects model was applied. These three analyses included

a handful of small studies, and the overall findings of the review are not altered by this sensitivity analysis.

The results of the review did not alter if risk ratio was applied as opposed to odds ratio.

DISCUSSION

Summary of main results

The aim of this Cochrane Review was to assess the evidence regarding the effectiveness of various methods for reducing STP following gynaecological laparoscopic procedures. This review is relatively complex in the sense that it has revealed an array of different interventions, often with subtle differences in how they are undertaken. It has also highlighted how studies assessing a common outcome such as incidence of STP, have often chosen very different time points post-operatively to do so. This has added another layer of complexity when pooling results. The 'Summary of findings' tables provide an ideal overview of the data alongside the quality of the evidence. [Summary of findings for the main comparison](#); [Summary of findings 2](#); [Summary of findings 3](#); [Summary of findings 4](#); [Summary of findings 5](#); [Summary of findings 6](#); [Summary of findings 7](#).

Below we summarise the results from the comparisons we have undertaken.

Comparison of a specific technique for releasing the pneumoperitoneum with a 'standard' technique

The overall analysis of women undergoing gynaecological laparoscopy suggests that a specific technique for releasing the pneumoperitoneum is associated with a reduction in the severity of STP, with less analgesia use, but not with an altered probability of experiencing STP, when compared with a standard technique for releasing the pneumoperitoneum. This finding also stands when we pool only results from studies examining the PRM versus standard technique.

These results should be interpreted with a degree of caution as the included studies are associated with a high risk of bias. As such, we graded the evidence as low quality.

The interventions utilised in this comparison (EAV, PRM, postural changes post-operatively and active intraperitoneal gas aspiration) are unlikely to cause morbidity and no adverse effects were reported in the single study that reported this outcome. Future studies should specifically assess adverse events before safety can be confirmed. The main concern being that of potential pulmonary injury with PRM.

Comparison of fluid instillation with no fluid instillation

Conclusions on this comparison are informed by two studies undertaken by one team of researchers in Taiwan. The analysis suggests that intraperitoneal fluid instillation is associated with a reduction in the incidence and severity of STP, and a reduction in analgesia requirements experienced by women undergoing gynaecological laparoscopy when compared with no fluid instillation.

The earlier study is at high risk of performance and detection bias due to lack of blinding. Therefore, the quality of the evidence is low to moderate, and the results should be interpreted with caution.

Comparison of an intraperitoneal drain with no intraperitoneal drain

The analysis of women undergoing gynaecological laparoscopy suggests that an intraperitoneal drain is associated with a reduction in the incidence of STP experienced, and a reduction in the use of analgesia post-operatively when compared with no drain or a dummy drain.

In the first few hours following surgery and at five to six days following surgery, there appears to be no evidence of a difference in the severity of STP experienced between the two groups. However, at all other time points examined in between (12, 24, 48 and 72 hours), there is an association between an intraperitoneal drain and a reduction in the severity of STP experienced when compared with no/dummy drain.

The quality of the evidence ranges from very low to moderate quality. This is because of a high risk of bias in the included studies owing to lack of a dummy/sham drain in half of the included studies, and inconsistency. The analgesia data comes from two small studies assessing different analgesic agents. In addition, no studies examined the quality-of-life scores from having an abdominal drain in situ, which is known to cause discomfort in some patients.

This is the only intervention that caused a reported complication.

Future studies should consider both pain-related impact of having an abdominal drain in situ and also its removal.

Comparison of subdiaphragmatic intraperitoneal local anaesthetic with a control

There was no evidence of a difference in the incidence or severity of STP experienced by women receiving subdiaphragmatic intraperitoneal local anaesthetic and women receiving no local anaesthetic. It should be noted that the quality of the evidence is low to moderate and that the nature of the interventions were all slightly different.

Two small included studies assessed analgesia usage. One study used paracetamol and the other used meperidine as the analgesic agent. The studies revealed low-quality evidence of an association between subdiaphragmatic local anaesthetic and reduced analgesia requirements post-operatively when compared with a control.

Comparison of local anaesthetic to the peritoneal cavity (not subdiaphragmatic) with a control

We included two studies in this comparison.

The pooled analysis of these two small studies suggests that local anaesthetic applied to the peritoneal cavity (not subdiaphragmatic) is associated with a reduction in the incidence of STP. The evidence is of low quality owing to a serious risk of bias and inconsistency, therefore this result should be interpreted with caution.

Comparison of warmed, or warmed and humidified insufflating gas with unwarmed and unhumidified insufflating gas

Three studies assessed severity of STP and analgesia usage post-operatively, but unfortunately only two studies published data on these two outcomes.

The pooled results revealed no evidence of a difference in the incidence, severity or analgesia requirements post-operatively between women receiving warm, or warmed and humidified insufflating gas and women receiving unwarmed and unhumidified insufflating gas. The quality of the evidence is moderate to high when assessing severity, but low when assessing incidence and analgesia usage, owing to small participant numbers and high risk of bias within these studies.

Comparison of gasless laparoscopy with carbon dioxide insufflation

Only one study assessed this comparison. The evidence from this one very small study suggests that gasless laparoscopy is associated with increased severity of STP post-operatively when compared with carbon dioxide insufflation. The evidence is of low to very low quality, owing to the single very small study, with high risk of bias and should be interpreted with extreme caution.

Comparison of an alternative insufflating gas versus carbon dioxide insufflation

We did not find any studies that undertook this comparison. Randomised controlled trials are required to determine the efficacy of an alternative insufflating gas on STP compared with carbon dioxide insufflation.

Overall completeness and applicability of evidence

The issue of post-operative STP for women undergoing gynaecological laparoscopy is common and has led to a number of varied interventions being developed to help relieve this symptom. The variety of interventions means that this review is large and some comparisons are well researched, whereas others have no RCTs to help guide decisions regarding their effectiveness.

The intervention of a 'specific' technique for releasing the pneumoperitoneum versus a 'standard' one is the most thoroughly researched comparison in this review, with nine included RCTs and large participant numbers. However, the interventions within this review are varied and heterogeneous. The pulmonary recruitment manoeuvre is the intervention that is the most well informed by RCTs. We were able to subgroup for this specific intervention, however it did not change the overall result, which indicated an association between a specific technique for releasing the pneumoperitoneum and a reduction in the severity of STP and analgesia requirements, but not the incidence of STP. In order to be confident of this finding, further studies assessing the poorly informed specific interventions, such as postural changes post-operatively, extended assisted ventilation and active intraperitoneal gas aspiration are required.

The remaining interventions in this review are less well informed by RCT data. The comparisons of a gasless laparoscopy with carbon dioxide insufflation, local anaesthetic to the peritoneal cavity (not subdiaphragmatic) with no local anaesthetic, and fluid instillation with no fluid instillation were informed by data from

only one or two included RCTs. We found no RCTs that used an alternative insufflating gas to carbon dioxide. These interventions are in particular need of further research in the form of properly powered RCTs. In the future, with further study data, we would like to subgroup these various interventions under the umbrella of a 'specific' technique for releasing the pneumoperitoneum.

The remaining three interventions that we examined (intraperitoneal drain, local anaesthetic to the subdiaphragm, and warmed and humidified gas) are informed by between three and seven RCTs. Owing to the disparate outcome measures in these, and all the included studies in this review, it is often difficult to combine data. We particularly struggled with the huge array of different time points at which severity of STP and the presence of STP were assessed. Likewise with analgesia usage, there were a variety of analgesic agents, in differing doses, all on a background of differing post-operative analgesia regimens. Encouraging the use of a core outcome set, such as those developed by CROWN (the Core Outcomes in Women's Health (CROWN) initiative; www.crown-initiative.org) for reporting in RCTs will help combine data from these studies in the future.

No included studies assessed delay in discharge or readmission rates, quality-of-life scores and directly related healthcare costs. It seems particularly important to address these outcomes in future RCTs, given that the incidence and severity of STP alone cannot be an accurate enough assessment of the efficacy of a particular intervention. Pain is a complex phenomenon, directly linked with quality of life and the perceived burden of a particular intervention or treatment. Future studies should consider reporting these outcomes in order to determine the overall efficacy of a particular intervention.

The women in this review are broadly representative of women undergoing gynaecological laparoscopy worldwide. This review includes younger women undergoing laparoscopy for fertility investigations, up to older women undergoing laparoscopic hysterectomy. The studies take place in differing healthcare systems, including Europe, Asia, the Middle East, Australasia, and the USA.

The indications for gynaecological laparoscopy are diverse, with some laparoscopies being purely diagnostic, with no operative procedure taking place, whereas others involve long and complex operations. This is likely to have an impact on the degree of STP experienced. Most studies were balanced in terms of the number of complex and lengthy operations in the intervention and control arms of their studies. Some studies include women undergoing laparoscopic hysterectomy. Opening the vaginal vault to remove the uterus during this operation allows gas to escape. This release of gas midway through the operation may affect the degree of STP experienced post-operatively. However, laparoscopic hysterectomy is a common indication for gynaecological laparoscopy and therefore including women undergoing this operation means that the evidence from this review is applicable to them.

Quality of the evidence

Thirty-two studies, with 28 included in quantitative analysis, met the inclusion criteria for this review. Using the GRADE approach, the overall quality of the evidence for each comparison ranged from very low to moderate (see the 'Summary of findings' tables:

Summary of findings for the main comparison; Summary of findings 2; Summary of findings 3; Summary of findings 4; Summary of findings 5; Summary of findings 6; Summary of findings 7.

The reasons for downgrading the evidence were risk of bias, imprecision and inconsistency, as we have described below.

Risk of bias

Imprecision

In all comparisons we downgraded the evidence for imprecision for outcomes where there were small numbers of included studies and consequently wide confidence intervals.

Inconsistency

We downgraded evidence for inconsistency in a number of comparisons including 'specific' versus a standard technique for releasing the pneumoperitoneum, intraperitoneal drain versus no drain and local anaesthetic to the peritoneal cavity versus no local anaesthetic. As a rule of thumb, if the I^2 value is $>50\%$, there is significant inconsistency and heterogeneity between study data.

Potential biases in the review process

We conducted a comprehensive search with the expert help of the Cochrane Gynaecology and Fertility Information Specialist, as well as extensive handsearching, in an effort to retrieve all eligible studies. We found four additional studies through handsearching (Benhamou 1994; Dobbs 1987; Liu 2014; Loughney 1994), but it is possible that we may not have identified further unpublished studies. We were unable to construct a funnel plot as fewer than 10 studies were available in any comparison, and therefore we were unable to estimate the existence of publication bias.

Although we contacted study authors for additional information, we could not obtain all of the requested information, which may have introduced bias due to the inclusion of studies with insufficient information. Furthermore, there remains the potential for study authors to provide inaccurate information and to provide overly positive data and answers to queries.

Agreements and disagreements with other studies or reviews

The conclusions that have been made as a result of this review are broadly consistent with other systematic reviews looking at similar interventions but in a general surgical patient population. The interventions being; local anaesthetic applied to the peritoneal cavity (Kahokehr 2011) and pulmonary recruitment manoeuvres (Pergialiotis 2015).

AUTHORS' CONCLUSIONS

Implications for practice

There is low to moderate-quality evidence that the following interventions are associated with a reduction in the incidence or severity, or both, of shoulder-tip pain (STP), or a reduction in analgesia requirements for women undergoing gynaecological laparoscopy: a specific technique for releasing the pneumoperitoneum; intraperitoneal fluid instillation; an intraperitoneal drain; and local anaesthetic applied to the peritoneal cavity (not subdiaphragmatic).

There is low to moderate-quality evidence that the following interventions may not make a difference to the incidence or severity of STP: subdiaphragmatic intraperitoneal local anaesthetic; and warmed and humidified insufflating gas.

There is low-quality evidence that gasless laparoscopy may increase the severity of STP, compared with standard treatment.

Few studies reported data on adverse events. Some potentially useful interventions have not been studied by randomised controlled trials (RCTs) of gynaecological laparoscopy.

Implications for research

Further large and more robustly designed studies for all interventions need to be undertaken to clarify these findings. In addition, studies should include reporting; delays in discharge, readmission rates, quality-of-life scores and directly related healthcare costs. Also, encouraging the use of a core outcome set, such as those developed by CROWN (the Core Outcomes in Women's Health (CROWN) initiative; www.crown-initiative.org) for reporting in RCTs will help combine data from these studies in the future. Interventions requiring more randomised evidence include post-operative postural changes, extended assisted ventilation, active intraperitoneal gas aspiration, gasless laparoscopy, local anaesthetic to the peritoneal cavity, fluid instillation and alternatives to carbon dioxide for insufflation.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Abbott 2001

Methods

Study: single-centre RCT

Country: UK

Type of surgery: diagnostic or minor laparoscopic procedure (laparoscopic sterilisation, hydrotubation, minor adhesiolysis, excision or ablation of stage I or II endometriosis, or aspiration of ovarian cyst)

Number and type of laparoscopic ports: umbilical port and additional ports as necessary

Distension medium and pressures: CO₂, 15 mmHg throughout the procedure

Study duration: not reported

Informed consent: yes

Funding sources: none reported

Abbott 2001 (Continued)

Participants	<p>A total of 225 women were enrolled in the study with complete data for 161 women. 82 women in the intervention group and 79 women in the placebo group</p> <p>Participants excluded: 14 were deemed unsuitable because more major surgery than planned was required, 32 had incomplete data sets, 5 were randomised but no drain was placed and 41 women did not return their questionnaire. Some women had more than one reason for exclusion.</p> <p>Age (mean \pm SD): intervention: 33.8 \pm 6.9, control: 33.8 \pm 7.1</p> <p>BMI (kg/m², mean \pm SD): intervention: 24.2 \pm 3.0, control: 23.7 \pm 3.1</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none">• Women undergoing diagnostic or minor operative laparoscopic procedure <p>Exclusion criteria</p> <ul style="list-style-type: none">• More extensive surgery was subsequently required
Interventions	<p>Intervention: single-bore Yeates gas drain (non-suction) for 4 h, placed into the pelvic cavity via either umbilical or accessory ports</p> <p>Control: dummy drain - achieved by coiling the Yeates drain over the wound site and covering in an opaque dressing</p>
Outcomes	<ul style="list-style-type: none">• Incidence of STP pre-op, 4, 24 and 48 h post-op• Adverse events
Notes	
Risk of bias	
Bias	Authors' judgement Support for judgement
Random sequence generation (selection bias)	Low risk Quote: "randomly assigned using computer-generated randomization blocks, stratified for procedure"
Allocation concealment (selection bias)	Low risk Quote: "Concealment was achieved by the allocation being placed in opaque envelopes, which were stored sequentially in operating rooms and opened by the nursing staff, when the entry criteria were satisfied." Comment: On further clarification with the author, it was confirmed that a nurses who opened the randomisation envelopes did not have any other roles in the study
Blinding of participants and personnel (performance bias) All outcomes	Low risk Women – Quote: "Drain was removed in a standardized way to reduce possibility of patient becoming aware of its location" Personnel – Quote: "Recovery staff members were unaware of the position of the drain as were the nursing personnel on the ward"
Blinding of outcome assessment (detection bias) All outcomes	Low risk Quote: "nurses blinded to the intervention administered the pain score prior to removal of the drain". Comment: outcome assessors were blinded. This blinding was confirmed on correspondence with the author
Incomplete outcome data (attrition bias)	Low risk Quote: "No differences in the demographic data were found for those patients excluded because of incomplete data sets".

Abbott 2001 (Continued)

All outcomes

Comment: high dropout rate with 73 randomised women not completing the study. Reasons for dropouts outlined and were reported as not related to the intervention.

Selective reporting (re-reporting bias)	Low risk	On correspondence with study author, all pre-determined outcomes were published
Other bias	Low risk	No other sources of bias identified

Alexander 1987

Methods	<p>Study: single-centre RCT</p> <p>Country: UK</p> <p>Type of surgery: laparoscopy for investigation of infertility or clip sterilisation</p> <p>Number and type of laparoscopic ports: not described</p> <p>Distension medium and pressures: CO₂, pressure not described</p> <p>Study duration: not described</p> <p>Informed consent: yes</p> <p>Funding sources: not described</p>
Participants	<p>Participants: 53 women, 25 in the intervention group and 28 in the control group</p> <p>Participants excluded: not described</p> <p>Age (mean ± SD): not described</p> <p>BMI (kg/m², mean ± SD): not described</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> Women undergoing routine laparoscopy for investigation of infertility or clip sterilisation <p>Exclusion criteria</p> <ul style="list-style-type: none"> Not described
Interventions	<p>Intervention: brief compression of abdominal wall and insertion of a 'suction catheter' (12 gauge Argyll PVC with end and side holes) on passive drainage through the umbilical port at the end of the procedure and left for 6 h</p> <p>Control: brief compression of abdominal wall to expel gas through open port and no 'suction catheter'</p>
Outcomes	<ul style="list-style-type: none"> Incidence of STP (unfortunately unable to use data as combined with abdominal and chest pain. Unable to contact study authors as have subsequently passed away) Severity of STP (unfortunately unable to use data as combined with abdominal and chest pain)
Notes	No data were extracted from this RCT

Risk of bias

Bias	Authors' judgement	Support for judgement
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Interventions to reduce shoulder pain following gynaecological laparoscopic procedures (Review)

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Alexander 1987 (Continued)

Random sequence generation (selection bias)	Unclear risk	Quote: "Assigned by random numbers". Comment: no description of how random numbers generated or how women received their allocation. 25 randomised to one group and 28 to the other
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women couldn't have been blinded due to lack of placebo in control group Surgeon could not be blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported questionnaires with help of a nurse if necessary. Unknown if nurse was blinded, but unlikely to make a difference given that women were unblinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition not described
Selective reporting (reporting bias)	High risk	No access to protocol or ability to ask study authors if all outcomes were reported Quote: "The distribution of pain scores was largely determined by the frequency of any pain and followed the same pattern" Comment: severity of pain was unreported
Other bias	Low risk	No other sources of bias identified

Benhamou 1994

Methods	Study: single-centre RCT Country: France Type of surgery: women undergoing laparoscopic sterilisation Number and type of laparoscopic ports: umbilical port and 'needle insertion' in lower right quadrant of abdomen. Additional port assumed to have been placed to complete laparoscopic procedure, but not outlined in paper. Distension medium and pressures: not reported Study duration: not reported Informed consent: yes Funding source: Astra® Pain control, a pharmaceutical company
Participants	50 women undergoing laparoscopic sterilisation: 25 in intervention group and 25 in the placebo group Participants excluded: unclear Age (years, mean \pm SD): intervention: 40.3 \pm 3.9, control: 38.6 \pm 3.8 BMI: not reported Ethnicity: not described

Interventions to reduce shoulder pain following gynaecological laparoscopic procedures (Review)

Benhamou 1994 (Continued)

Inclusion criteria

- Women scheduled for Yoon ring sterilisation

Exclusion criteria

- Heart disease
- History of laparotomy

Interventions	<p>Intervention: following insertion of primary trocar and laparoscope and prior to sterilisation; 80 mL 0.5% lidocaine with 1/320,000 epinephrine was instilled intraperitoneally into the right subdiaphragmatic quadrant via a laparoscopic ovarian cyst drainage needle placed transcutaneously. At the end of the operation, 10 mL of 2% lidocaine with 1/80,000 epinephrine was injected into each mesosalpinx.</p> <p>Control: the control group received normal saline instead of lidocaine, instilled using the same technique.</p>
Outcomes	<ul style="list-style-type: none"> • Analgesia usage (number of 500 mg paracetamol tablets taken in first 48 h) • Adverse events directly related to intervention • Severity of STP (unfortunately unable to use these data in meta-analysis as data displayed on small graph without clear SDs. Following correspondence with the study author it was confirmed that no data were saved to enable us to include this outcome.
Notes	Correspondence with study authors via email November 2015. Informed that original data no longer available. Unable to answer further queries.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "using a table of random numbers"
Allocation concealment (selection bias)	Unclear risk	Method of concealment not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	<p>Quote: "Both anaesthetist and surgeon were blinded to the injected drug". Comment: no further explanation of how this was achieved. There is no description of when and who made the injections up.</p> <p>Comment: study is described as being double-blind. We do not know whether participants were also blinded.</p>
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Post-op questionnaires used, self-administered
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No mention of incomplete data from attrition or exclusion, however women were asked to mail their questionnaires back from home. Unlikely that all women did this. Asked study authors to clarify, but no response
Selective reporting (reporting bias)	Unclear risk	No protocol available and study authors did not confirm whether all outcomes reported
Other bias	Low risk	No other sources of bias identified

Chou 2005

Methods	<p>Study: single-centre RCT</p> <p>Country: Taiwan</p> <p>Type of surgery: gynaecological laparoscopic procedures, including electrocautery for pelvic endometriosis, tubal sterilisation, adhesiolysis, ovarian cystectomy, and tubal reconstructive surgery</p> <p>Number and type of laparoscopic ports: 10 mm infra-umbilical trocar x 1 and 5 mm supra-pubic trocars x 2</p> <p>Distention medium and pressures: 15 mmHg CO₂</p> <p>Study duration: 1 year</p> <p>Informed consent: yes</p> <p>Funding sources: Chang Gung Memorial Hospital research grant</p>
Participants	<p>91 women enrolled and were randomised into 3 groups A (n = 30), B (n = 30) and C (n = 31)</p> <p>Participants excluded: 12 women were excluded post-randomisation, 4 from group A, 4 from group B and 4 from group C. Reasons cited were: 4 had severe endometriosis, 3 underwent a concomitant culdotomy, 2 had an operative time of more than 3 h, and 3 had a pelvic drain placed post-op.</p> <p>Age (years, mean ± SD): A 31.1 ± 10.6, B 31.6 ± 7.9, C 35.1 ± 11.0</p> <p>BMI (kg/m², mean ± SD): A 21.3 ± 2.9, B 22.8 ± 3.5, C 21.5 ± 3.7</p> <p>Ethnicity: not reported</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> Gynaecological laparoscopic surgery ASA 1-2 <p>Exclusion criteria</p> <ul style="list-style-type: none"> History of laparotomy, Severe endometriosis (AFS score > 40) Extensive pelvic adhesions Operative time of > 3 h, Ruptured ectopic with haemoperitoneum Active intraperitoneal infection with concomitant culdotomy Insertion of a post-op drain
Interventions	<p>Specific intraperitoneal infusion interventions; all whilst in Trendelenberg position</p> <p>Intervention A: 50 mL Ringer's lactate solution immediately after trocar insertion (pre procedure) and 40 mL Ringer's lactate solution with 10 mL 0.5% bupivacaine with epinephrine (1:500) post-procedure</p> <p>Intervention B: 40 mL Ringer's lactate solution with 10 mL 0.5% bupivacaine with epinephrine (1:500) given pre- and post-procedure</p> <p>Control group C: 50 mL Ringer's lactate solution given pre- and post-procedure.</p> <p>In each group the fluid instilled was divided as follows: 30 mL into the subdiaphragmatic space, (15 mL on the left and 15 mL on the right), with 20 mL instilled into the pelvic cavity. The fluid was left in situ "for at least 5 minutes".</p> <p>Quote: "At the conclusion of the procedure as much CO₂ as possible was removed from the peritoneal cavity"</p>

Chou 2005 (Continued)

- Outcomes
- Severity of STP using VAS score at 2, 4, 8 and 16 h
 - Analgesia usage (meperidine consumption (mg) in first 24 h)

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly assigned 1:1:1 to the A, B or C group according to preprinted slips on sealed envelopes that had been prepared at the start of the study using a computer-generated randomization schema"
Allocation concealment (selection bias)	Low risk	On correspondence with study authors, it was confirmed that the scrub nurse in theatre that day, who was not involved in any other aspect of the study, was responsible for opening the sealed envelope in theatre.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "As well as the patient, neither the surgeon nor the assessor of pain was aware of the solution administered"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "neither the patients nor the post-operative caregivers were aware of the solution administered". Comment: additionally, women self-administered the VAS pain score
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons for exclusion outlined and were in keeping with pre-defined exclusion criteria
Selective reporting (reporting bias)	High risk	Quote: "because many patients (28/79) were discharged less than 24 h post-op, the analysis of pain at 24 h was omitted for the consideration of small sample" Comment: failure to report pre-defined outcome. Regarding STP; according to the methods, pain at 24 h was to be reported.
Other bias	Low risk	No other sources of bias identified

Dobbs 1987

Methods

Study: single-centre RCT

Country: UK

Type of surgery: non-urgent gynaecological laparoscopy

Number and type of laparoscopic ports: not reported

Distention medium and pressures: CO₂, pressure not recorded

Study duration: not reported

Informed consent: yes

Funding sources: not reported

Dobbs 1987 (Continued)

Participants	<p>131 Women (67 in intervention group, 64 in control group)</p> <p>Participants excluded: none</p> <p>Age (years, mean \pm SD): not reported</p> <p>BMI (kg/m², mean \pm SD): not reported</p> <p>Ethnicity: not reported</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> Non-urgent gynaecological laparoscopy <p>Exclusion criteria</p> <ul style="list-style-type: none"> If proceeded to laparotomy If medical condition relative contraindication for head-down tilt
Interventions	<p>Intervention: post-op nursing in 30° head-down tilt for 30 min and left lateral</p> <p>Control: post-op nursing in flat position and left lateral</p>
Outcomes	<ul style="list-style-type: none"> Incidence of STP within 72 h post-op Severity of STP using a VAS score (1-10) at 2, 6 and 18-24 h post-op and at 14.00 on the day of discharge (day 1), day 2 and day 3. Unfortunately these data were not published and therefore unable to use in meta-analysis
Notes	Unfortunately corresponding author now deceased so unable to obtain further clarification or data on this study.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "patients were allocated by random numbers"
Allocation concealment (selection bias)	Unclear risk	Allocation of women was undertaken on arrival in the theatre. No further information on who undertook this, or how allocation was concealed was provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>Quote: "The treatment method was unknown to the patients, ward staff and the post-operative investigator".</p> <p>Comment: blinding of women was probably broken as the patient woke from anaesthesia because they were nursed either tilted or flat for 30 min in the recovery room before being laid flat and transferred to the ward.</p> <p>The surgeon was "unaware of the chosen post-operative treatment" until after abdominal closure</p>
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Self-reported questionnaires and women unblinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Very high attrition rate. Questionnaire not returned by 25% of the intervention group and 14% of the control group

Dobbs 1987 (Continued)

Selective reporting (reporting bias)	High risk	VAS scores for STP not reported
Other bias	Low risk	No other sources of bias identified

Guido 1998

Methods	<p>Study: multicentre RCT</p> <p>Country: USA</p> <p>Type of surgery: laparoscopic tubal ligation</p> <p>Number and type of laparoscopic ports: single infra-umbilical port</p> <p>Distention medium and pressures: intervention group - no distension, control group - CO₂, pressure 15 mmHg</p> <p>Study duration: 25 months</p> <p>Informed consent: yes</p> <p>Funding sources: not reported</p>
Participants	<p>67 women were randomised (unknown how many to each group, 54 complete data sets, 30 in intervention group, 24 in control group)</p> <p>Participants excluded: 13 women were lost to follow-up or did not return their questionnaires.</p> <p>Age (years, mean): intervention 31, control 30</p> <p>BMI: not reported</p> <p>Ethnicity: only reported that 9/24 control group and 9/30 of the intervention group were 'African-American'</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • ≥ 18 years • Undergoing laparoscopic tubal ligation • Spoke English • Had access to a telephone for follow-up communication • were able to read and understand the consent forms • Had a haemoglobin > 10 mg/dL • Negative urine pregnancy test <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Medical condition precluding general anaesthesia • Known allergy to any of the protocol anaesthetics • Contraindication to laparoscopy • Weight > 200 lbs (approximately 90 kg) • contraindication to an umbilical incision
Interventions	<p>Intervention: use of 'Laprolift' system. Quote: "A transverse incision was made just caudad to the umbilicus and dissected down to the anterior rectus fascia which was incised transversely. The rectus muscles were separated in the midline and the peritoneum entered under direct visualisation. A 10cm Laprofan was inserted under tactile guidance and connected to the laprolift. The anterior abdominal</p>

Guido 1998 (Continued)

wall was initially elevated to allow placement of an 11-mm cannula sheath and a laparoscope under the laprofan. Correct placement of the laprofan was confirmed visually before the abdominal wall was elevated to its final position for the surgical procedure". Tubal ligation was then undertaken as in the control group

Control: 'conventional' CO₂ laparoscopy via Veress needle placed infra-umbilically

Outcomes	<ul style="list-style-type: none"> Severity of STP using VAS score (0-30) before discharge from hospital, the evening of surgery and post-op days 1, 2, 3, 7 and 14. Unfortunately unable to use data from day of surgery, and of days 7 and 14 in meta-analysis as not reported Adverse events^a. Unable to input data as ITT as original numbers of women randomised to each group is unknown.
Notes	<p>^aIntervention group: 1 laparotomy for bleeding from the fallopian tube, 2nd woman developed an omental haematoma as a direct result of entrapment while placing Laprofan, 1 uterine perforation during placement of uterine manipulator</p> <p>Control group: 1 laparotomy for internal iliac laceration with Veress needle, 1 uterine perforation during placement of uterine manipulation</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Women were randomised by a computer-generated table by a third party"
Allocation concealment (selection bias)	Low risk	Quote: "Group assignments were placed in sealed opaque envelopes and drawn in sequence"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind surgeon. Study described as 'single blind'. Unsure who exactly this was. No response on emailing study authors
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Self-administered questionnaires, however unsure if women were blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	67 women were randomised. 13 women were lost to follow-up or did not return their VAS scores. 54 women completed VAS scores for all post-op days (1, 2, 3, 7 and 14 days). Despite the high attrition, study authors did explain that they attempted to obtain a full data set by telephoning women requesting they return their VAS scores. Study participant demographics remain even
Selective reporting (reporting bias)	High risk	No data reported on VAS pain scores on day of surgery, day 7 or 14
Other bias	Low risk	No other sources of bias identified

Haghgoo 2016

Methods	Study: single-centre RCT
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Haghgoo 2016 (Continued)

Country: Iran

Type of surgery: uncomplicated gynaecological laparoscopy (included resection of endometriosis, resection of ovarian cyst walls, myomectomy, hysterectomy and 'other' procedures)

Number and type of laparoscopic ports: 4 ports: 11 mm umbilical port x 1, 5 mm lateral ports x 2 and 11 mm suprapubic port x 1

Distention medium and pressures: CO₂, pressure 12-17 mmHg

Study duration: 27 months

Informed consent: yes

Funding sources: not reported

Participants	<p>92 women were randomised: 46 in intervention group, 46 in control group</p> <p>Participants excluded: 3 women were lost to follow-up; 2 in the intervention group and 1 in the control group</p> <p>Age (years, mean \pm SD): intervention 38.3 \pm 8.9, control 36.8 \pm 8.1</p> <p>BMI: (kg/m², mean \pm SD): intervention 25.4 \pm 5.3, control 24.9 \pm 5.2</p> <p>Ethnicity: not reported</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • 22-64 years of age • Undergoing uncomplicated gynaecological laparoscopic procedures at Pars Hospital, Tehran, Iran April 2012-July 2014 <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Pre-op shoulder, abdominal or pelvic pain • Systemic disease • Severe abdominal and pelvic adhesion detected before or during the operation • Tubo-ovarian abscess detected before or during the operation • Women who needed drainage because of organ injury, bleeding or infection
Interventions	<p>Intervention: intra-peritoneal drain (Hemovac) placed under direct vision at end of operation via suprapubic port site, under passive drainage. It was in place for \geq 24 h</p> <p>Control: no drain inserted</p>
Outcomes	<ul style="list-style-type: none"> • Incidence of STP at 12, 24 and 48 h post-op • Severity of STP using 10-point VAS score at 12, 24 and 48 h post-op • Analgesia requirements (100 mg diclofenac) over 48-h period • Adverse events
Notes	<p>ITT analysis undertaken for incidence of STP</p> <p>Actual numbers of women in each group as denominators for continuous variables (analgesia usage and severity of STP)</p> <p>Unknown if hysterectomy was total laparoscopic or LAVH</p> <p>Emailed study authors May 2017 but no response</p>

Risk of bias

Haghgoo 2016 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "computerised block randomisation table"
Allocation concealment (selection bias)	Unclear risk	Quote: "sealed envelopes handed to surgeon". Comment: no mention of numbered envelopes therefore unclear risk
Blinding of participants and personnel (performance bias) All outcomes	High risk	Surgeon and women were not blinded owing to nature of intervention (drain vs no drain)
Blinding of outcome assessment (detection bias) All outcomes	High risk	Pain scores were recorded by independent observers not aware of study design and objectives, but may not have been blinded to intervention. Additionally, women not blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low rate of attrition in both arms (2 from intervention arm, 1 from control arm)
Selective reporting (reporting bias)	Unclear risk	Contacted study authors May 2017 to establish if all outcomes published, but no response
Other bias	Low risk	No other sources of bias identified

Herrmann 2015

Methods	<p>Study: single-centre RCT</p> <p>Country: Germany</p> <p>Type of surgery: LAVH with or without laparoscopic oophorectomy</p> <p>Number and type of laparoscopic ports: 3 ports: 10 mm umbilical port x 1, 5 mm lateral ports x 2</p> <p>Distention medium and pressures: CO₂, pressure 14 mmHg</p> <p>Study duration: 9 months</p> <p>Informed consent: yes</p> <p>Funding sources: the humidification sets used in the study were provided by Fisher & Paykel Healthcare Ltd, but no financial grant, study support, or honorarium was provided by this company</p>
Participants	<p>104 women were randomised: 52 in intervention group, 52 in control group</p> <p>Participants excluded: 4 women in the intervention group and 3 women in the control group were excluded from the study after randomisation. Reasons for those women in the intervention group included that laparoscopy was not possible due to obesity, an allergic reaction to morphine, and intra-operative decision against LAVH due to severe endometriosis and severe adhesions. Reasons for those women in the control group included unblinding of study personnel, and post-op bleeding requiring re-operation on post-op day 1.</p> <p>Age (years, mean \pm SD): intervention 47 ± 8.2, control 46.7 ± 7.0</p> <p>BMI: (kg/m², mean \pm SD): intervention 28.9 ± 5.8, control 25.6 ± 3.7</p>

Herrmann 2015 (Continued)

Ethnicity: not reported

Inclusion criteria

- ≥ 18 years
- Benign uterine condition
- ≥ 1 vaginal delivery
- Ability to understand the study procedure
- Sonographic estimation of uterus weight < 400 g
- Pre-op estimation of surgery time between 1 and 2 h

Exclusion criteria

- Previous surgeries that indicate extensive cicatrisation
- Previous laparotomy
- Current cancer
- Concurrent chronic disease requiring analgesics

NB, After 3.5 months of recruitment, a decision was made to include women with a history of no vaginal birth

Interventions	<p>Intervention: pneumoperitoneum with warm ($35 \pm 2^\circ\text{C}$), humidified (98% humidity) CO_2</p> <p>Control: pneumoperitoneum with cold (room temperature), dry (0% humidity) CO_2</p>
Outcomes	<ul style="list-style-type: none"> • Incidence of STP post-op within 48 h. Data used on ITT basis for this review • Severity of STP using 10-point VAS score at 2, 4, 6, 24 and 48 h post-op. Data provided as means and SDs on communication with study authors • Analgesia requirements as morphine consumption over total length of stay. Data provided as means and SDs on communication with study authors • Adverse events
Notes	We contacted study authors May 2017, who kindly provided the requested data

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was effected with RITA (Randomization in Treatment Arms) soft ware, version 1.27. Permuted-block randomization with block length of 4 and 6 was used."
Allocation concealment (selection bias)	Low risk	Quote: "Based on the randomization list generated with RITA, an independent, external person prepared sequentially numbered, opaque, sealed envelopes. Envelopes were labelled with the respective randomization list number (subjects 1, 2, 3, etc.). Envelopes were stored in a locked room and handed to OR staff by the study nurse shortly before surgery and after induction of anaesthesia."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Women and study nurses responsible for recording pain scores were blinded. Surgeon and theatre staff could not be blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Women and study nurses responsible for recording pain scores were blinded.

Herrmann 2015 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Low rate of attrition (7 women in total) and all dropouts accounted for
Selective reporting (reporting bias)	Low risk	Study author confirmed all outcomes published
Other bias	Low risk	No other sources of bias identified

Johnson 1994

Methods	<p>Study: single-centre RCT</p> <p>Country: UK</p> <p>Type of surgery: women undergoing gynaecological laparoscopy (diagnostic, tubal patency testing, Filshie clip sterilisation, adhesiolysis, cyst aspiration and cervical cauterization)</p> <p>Number and type of laparoscopic ports: not reported</p> <p>Distention medium and pressures: not reported</p> <p>Study duration: 1989-Feb 1990</p> <p>Informed consent: yes</p> <p>Funding sources: not reported</p>
Participants	<p>80 women were randomised: 40 in intervention group, 40 in control group</p> <p>Participants excluded: 3 women were excluded; 1 in the intervention group because the consent form was inadequate and 2 in the control group because the treatment vials were accidentally broken before the participant went to theatre.</p> <p>Age (years, mean \pm SD): not reported</p> <p>BMI: (kg/m², mean \pm SD): not reported</p> <p>Ethnicity: not reported</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> Women undergoing gynaecological laparoscopy <p>Exclusion criteria</p> <ul style="list-style-type: none"> Women undergoing oocyte collection
Interventions	<p>Intervention: 10 mL of 0.5% bupivacaine infused through the insufflation portal of the umbilical laparoscopic trocar during withdrawal. Intention was to bathe peritoneal folds, and extraperitoneal and subcutaneous fat in both groups.</p> <p>Control: 10 mL of 0.9% saline infused through the insufflation portal of the umbilical laparoscopic trocar during withdrawal</p>
Outcomes	<ul style="list-style-type: none"> Severity of STP using VAS (0-120 mm) at 30 min, 2 h, 4 h and 16-20 h post-op Unfortunately we were unable to use these data as only available on graph without SDs Analgesia requirements (doses of Omnopon, paracetamol and diclofenac). Unfortunately we were unable to use these data in meta-analysis as doses and timescale of analgesia usage was not available

Johnson 1994 (Continued)

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Block randomisation code"
Allocation concealment (selection bias)	Low risk	Quote: "The master code was held by an independent observer and the vials were indistinguishable from each other apart from their code".
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Surgeon, members of theatre staff and women were blinded". Comment: self-administered pain scores
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-administered pain scores. Women blinded. On communication with study author, blinding was not broken until after data were analysed
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition rate (3 overall) with clear explanations for excluded women
Selective reporting (reporting bias)	Low risk	No access to protocol. Contacted lead author to clarify May 2017 who confirmed there were no unpublished data.
Other bias	High risk	There were significant differences in the patient characteristics between the 2 groups. For example more women underwent an operative laparoscopy in the control group compared to the intervention group. Additionally, more women had undergone previous surgery in the control group. These factors may have influenced pain experienced.

Kafali 2004

Methods	<p>Study: single-centre RCT</p> <p>Country: Turkey</p> <p>Type of surgery: minor gynaecological laparoscopic procedures, including diagnostic laparoscopy, laparoscopic sterilisation, minor adhesiolysis and ovarian drilling</p> <p>Number and type of laparoscopic ports: not reported</p> <p>Distention medium and pressures: CO₂, pressure set at 15 mmHg</p> <p>Study duration: not reported</p> <p>Informed consent: yes</p> <p>Funding sources: not reported</p>
Participants	<p>46 women undergoing minor gynaecological laparoscopic procedures: 24 in control group, 22 in intervention group</p> <p>Participants excluded: not reported</p>

Kafali 2004 (Continued)

Age (years, mean \pm SD): intervention 28.6 ± 7.5 , control 30.1 ± 6.7

BMI (kg/m², mean \pm SD): not reported

Ethnicity: not reported

Inclusion criteria

- Any woman undergoing minor gynaecological procedures

Exclusion criteria

- None reported

Interventions	<p>Intervention group: an 'aspiration cannula' was inserted through an accessory port and orientated towards the subdiaphragmatic space. The gas was released by opening the gas port and also 'removal of cannula cap' with patient in Trendelenberg position.</p> <p>Control: the pneumoperitoneum released by opening the gas port ('passive evacuation')</p>
Outcomes	<ul style="list-style-type: none"> Severity of STP using VAS (VAS not described) at 6, 12 and 24 h post-op Analgesia requirements (tramadol)
Notes	<p>No communication received back regarding exclusions/attrition, VAS range</p> <p>No communication back regarding complications or queries regarding technique</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Computer-generated randomisation blocks, stratified for procedure."
Allocation concealment (selection bias)	Unclear risk	None described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	None described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear as to who was involved in assessing outcome, but likely to be self-administered questionnaires for severity of STP. Analgesia was administered by a nurse who "was unaware of the randomisation"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No exclusions/attrition were described
Selective reporting (reporting bias)	Unclear risk	No access to protocol and unable to contact study authors to clarify
Other bias	Low risk	No other sources of bias identified

Keita 2003

Methods	Study: single-centre RCT
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Keita 2003 (Continued)

Country: France

Type of surgery: laparoscopic gynaecological surgery including treatment of tubal infertility, chronic salpingitis, suspected endometriosis or ovarian disease

Number and type of laparoscopic ports: not reported

Distention medium and pressures: not reported

Study duration: not reported

Informed consent: yes

Funding sources: grants from Assistance Publique-Hospitaux de Paris, France

Participants	<p>72 women undergoing gynaecological laparoscopic procedures were randomised to 4 different groups (18 in each). 3 intervention groups versus 1 control group</p> <p>Participants excluded: 7 women were excluded: 3 from group A (bupivacaine), 2 from group B (morphine), and 2 from group D (control). For 3, the reason was conversion to open surgery, for 2 the surgeon had to aspirate the solution early due to bleeding and 2 needed a myomectomy</p> <p>Age (years, mean): group A 33, group B 32, group C 32.5, group D 32.5</p> <p>BMI (kg/m², mean ± SD): not reported</p> <p>Ethnicity: not reported</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • Aged 18-40 years • ASA 1-2 • Scheduled for gynaecological laparoscopic surgery <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Presenting for emergency operation • History of malignancy • Contraindication to taking NSAIDs and paracetamol • Confirmed allergy to local anaesthetic
Interventions	<p>The surgeon sprayed 12 mL solution into the right subdiaphragmatic area and 11 mL into the pelvic cavity under visual control immediately after creating the pneumoperitoneum and before starting the surgery</p> <p>Intervention group A (bupivacaine): 20 mL 0.5% bupivacaine with epinephrine 1:200,000 and 3 mL 0.9% saline</p> <p>Intervention group B (morphine): 3 mg morphine and 20 mL 0.9% saline</p> <p>Intervention group C (bupivacaine and morphine): 20 mL 0.5% bupivacaine with epinephrine 1:200,000 and 3 mg morphine</p> <p>Control group D: 23 mL 0.9% saline</p>
Outcomes	<ul style="list-style-type: none"> • Incidence of STP within 24 h post-op • Severity of STP using 10-point VAS score (unfortunately unable to use these data as mixed with other types of pain including abdominal) • Analgesia usage (unfortunately unable to use these data as not specifically for STP)
Notes	<p>Contacted study authors May 2017 but no response</p> <p>Control group split 3 ways to accommodate 3 intervention groups</p>

Keita 2003 (Continued)

ITT (18 women per group)

Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Random number table".
Allocation concealment (selection bias)	Low risk	Quote: "Test solutions were drawn into 4 coded syringes by the pharmacist".
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The anaesthetist, surgeon and nurses were unaware of patient allocation. Not explicitly described whether women were blinded, however study called "double-blind"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-reported pain and women very likely to be blinded. Nurses administering analgesia were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Approx 10% attrition. Reasons clearly explained
Selective reporting (reporting bias)	Unclear risk	No access to protocol and unable to contact study authors. We have extrapolated numbers of women who experienced STP from percentages in table II. These percentages do not easily translate into a whole number. We have had to round up or down. This may represent reporting bias.
Other bias	Low risk	No other sources of bias identified

Kim 2014

Methods	Study: RCT. Unsure if single-centre or multicentre Country: Republic of Korea Type of surgery: "gynaecological laparoscopy", no further information available Number and type of laparoscopic ports: not reported Distension medium and pressures: not reported Study duration: not reported Informed consent: not reported Funding sources: not reported
Participants	287 women undergoing gynaecological laparoscopic procedures Participants excluded: not reported Age (years, mean \pm SD): not reported BMI (kg/m ² , mean \pm SD): not reported Ethnicity: not reported

Kim 2014 (Continued)

Inclusion criteria

- Not reported

Exclusion criteria

- Not reported

Interventions	<p>287 women were randomised to 1 of 4 groups.</p> <p>Group A intraperitoneal instillation of bupivacaine</p> <p>Group B, CO₂ removal by a PRM consisting of 5 manual inflations of the lung with a maximum pressure of 30 cm H₂O</p> <p>Group C, combination of intraperitoneal bupivacaine and PRM</p> <p>Group D, placebo</p> <p>The interventions were performed at the end of surgery.</p>
Outcomes	<ul style="list-style-type: none"> • Severity of STP on a VAS at 1, 6, 12, and 24 h post-op. VAS score not described. Unable to use data in meta-analysis (see below) • Incidence of STP. Unable to use data in meta-analysis (see below)
Notes	<p>This paper is a conference abstract with minimal details of the methodology of the study. Additionally, we cannot determine how many women were randomised to each group, making extraction of data impossible. We contacted the first author by email 11/4/17</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	This is a very brief conference abstract of an RCT. The details of the methodology or results are not described in any detail making all judgements on bias almost impossible
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No details on results or how many women were randomised to each group. Full results not available
Selective reporting (reporting bias)	Unclear risk	Unable to determine as protocol not available and unable to contact authors
Other bias	Unclear risk	Unable to determine due to limited information from brief conference abstract

Kissler 2004

Methods	<p>Study: single-centre RCT</p> <p>Country: Germany</p> <p>Type of surgery: gynaecological laparoscopic surgery of the adnexa or adhesiolysis</p> <p>Number and type of laparoscopic ports: 12 mm port for the laparoscope. Size of other ports not reported</p> <p>Distention medium and pressures: CO₂, pressure set at 12 mmHg</p> <p>Study duration: not reported</p> <p>Informed consent: yes</p> <p>Funding sources: pneumoperitoneum was established with a Laparo-CO₂-Pneu 2232 (Wolf, Knittlingen, Germany), which was donated by the manufacturer. No further financial support was granted.</p>
Participants	<p>90 women undergoing gynaecological laparoscopic procedures were randomised into 3 groups, however the study was stopped early after 53 women had taken part, because no significant pain reduction could be observed in intervention groups A and B compared with the control group. Group A (heated, humidified gas) included 17 women, Group B (heated gas) included 17 women, Group C (cool, dry gas, control) included 19 women.</p> <p>Participants excluded: not reported</p> <p>Age (years, mean \pm SD): group A 37 ± 7.5, group B 33 ± 7.6, group C (control) 36 ± 13.4</p> <p>BMI (kg/m², mean \pm SD): not reported</p> <p>Ethnicity: not reported</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> Any woman scheduled for gynaecological laparoscopic procedures <p>Exclusion criteria</p> <ul style="list-style-type: none"> None reported
Interventions	<p>Intervention group A: humidified and heated (38°C) CO₂ insufflation gas</p> <p>Intervention group B: dry and heated (38°C) CO₂ insufflation gas</p> <p>Control group C: dry and unheated insufflation gas</p>
Outcomes	<ul style="list-style-type: none"> Incidence of STP at 2 and 6 h, and day 1 post-op (only data on incidence overall were published) Severity of STP on a VAS score (0-10) at 2 h, 6 h and 1 day post-op (results not published in paper so unable to use in meta-analysis) Analgesia requirements (median doses published, so unable to use these data in meta-analysis)
Notes	<p>Emailed study authors April 2017 for further information, but no response.</p> <p>Incidence of STP data analysed on ITT basis (30 women randomised per group). Control group split between the 2 interventions.</p>
Risk of bias	
Bias	<p>Authors' judgement Support for judgement</p>

Kissler 2004 (Continued)

Random sequence generation (selection bias)	Low risk	Quote: "randomisation was performed by means of a computer-generated randomisation list."
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Women, data-analyst, and interviewer were all blinded to randomisation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewer blinded to intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: [participants] "did not differ in terms of age, weight and duration of surgery." Comment: participants who received the intervention had similar demographics Comment: study terminated prematurely, so some randomised participants never received the intended intervention.
Selective reporting (reporting bias)	High risk	Study terminated prematurely after inappropriate interim analysis of results. Did not report VAS scores. Did not report incidence of STP at time intervals described in methods. Did not report analgesia usage other than as median score per randomised group.
Other bias	High risk	Study stopped early based on interim data analysis revealing no significant difference in reduction of pain scores in both intervention groups versus the control group. Small study with attrition of over 1/3 of randomised women. Deviation from study protocol - randomised women did not receive intended intervention

Kocamanoglu 2005

Methods	Study: single-centre RCT Country: Turkey Type of surgery: diagnostic or minor gynaecological laparoscopic surgery Number and type of laparoscopic ports: not reported Distention medium and pressures: not reported Study duration: not reported Informed consent: yes Funding sources: not reported
Participants	55 women undergoing diagnostic or minor gynaecological laparoscopic procedures were randomised into 3 groups. Group A (bupivacaine 20 mL 0.5%) included 17 women, group B (ropivacaine 20 mL 0.75%) included 18 women, group C (control, no intraperitoneal injection) included 20 women Participants excluded: not reported

Kocamanoglu 2005 (Continued)

Age (years, mean \pm SD): group A 26.82 ± 5.85 , group B 28.27 ± 7.04 , group C (control) 27.10 ± 5.63

BMI (kg/m², mean \pm SD): not reported

Ethnicity: not reported

Inclusion criteria

- Women undergoing diagnostic or minor operative laparoscopic procedures

Exclusion criteria

- None reported

Interventions	<p>Intervention group A: 20 mL 0.5% bupivacaine mixed with 60 mL saline injected into right subdiaphragmatic (30 mL) and abdominopelvic space (50 mL)</p> <p>Intervention group B: 20 mL 0.75% ropivacaine mixed with 60 mL saline injected into right subdiaphragmatic (30 mL) and abdominopelvic space (50 mL)</p> <p>Intervention group C (control): didn't receive any solution intraperitoneally</p>
Outcomes	<ul style="list-style-type: none"> • Incidence of STP by 24 h post-op • Severity of STP using VAS score (unfortunately these data were combined with abdominal pain on the VAS score, so we were unable to use in meta-analysis) • Adverse events
Notes	<p>Turkish to English translation kindly undertaken by Aytug Our</p> <p>The term 'injected' in this paper is assumed to mean 'sprayed' onto peritoneal surface, not passed through a needle into the peritoneum. This assumption is supported by lack of description of a needle.</p> <p>Emailed study authors for further information April 2017, but no response</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Study described as 'double-blind'. No further description available
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The researcher assessing STP was blinded to the intervention
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram of women not available
Selective reporting (reporting bias)	Unclear risk	No study protocol available

Kocamanoglu 2005 (Continued)

Other bias	Low risk	No other sources of bias identified
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Leelasuwattanakul 2016

Methods	<p>Study: single-centre RCT</p> <p>Country: Thailand</p> <p>Type of surgery: diagnostic laparoscopy and tubal patency testing</p> <p>Number and type of laparoscopic ports: 5 mm ports x 3; 1 at umbilicus and 2 in suprapubic area</p> <p>Distention medium and pressures: warmed CO₂ to max pressure of 12 mmHg</p> <p>Study duration: 8 months</p> <p>Informed consent: yes</p> <p>Funding sources: funded by the Faculty of Medicine, Chulalongkorn University, Thailand</p>
Participants	<p>74 infertile women undergoing diagnostic laparoscopy and tubal patency testing with methylene blue +/- electro-cauterisation of endometriosis if found. 37 women were randomised into the intervention group (active gas aspiration) and 37 into the control group (simple gas evacuation)</p> <p>Participants excluded: not reported</p> <p>Age (years, mean ± SD): intervention 32.5 ± 4.2, control 33.2 ± 4.0</p> <p>BMI (kg/m², mean ± SD): intervention 21.1 ± 2.4, control 22.0 ± 2.7</p> <p>Ethnicity: not reported</p> <p>Inclusion criteria: infertile women undergoing diagnostic laparoscopy and tubal patency testing, ASA class I</p> <p>Exclusion criteria: pregnancy, history of analgesia drug use within 48 h prior to the operation, history of upper abdominal surgery, and if other operative procedures were performed during surgery, except electro-cauterisation in pelvic endometriosis</p>
Interventions	<p>Intervention: Trendelenburg position, all trocars opened and an aspiration cannula was placed at the subdiaphragmatic area under direct visualisation, CO₂ flow stopped, residual gas was removed by suctioning at 100 mmHg</p> <p>Control: Trendelenburg position, CO₂ flow stopped, all trocars opened and the surgeon applied abdominal pressure to evacuate any residual CO₂</p>
Outcomes	<ul style="list-style-type: none"> Analgesia requirements (we were unable to use these data in meta-analysis as the paper did not state over what time period the analgesia was taken. We asked the study authors but they didn't respond on this) Adverse events Severity of STP on a VAS score (0-10) at 6, 12, and 24 h (unfortunately data presented as median and range, so unable to use in meta-analysis)
Notes	<p>Emailed study authors for further information April 2017, and responses have guided risk of bias assessment</p>

Risk of bias

Leelasuwattanakul 2016 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Computer randomisation'
Allocation concealment (selection bias)	Unclear risk	After contacting study authors, quote: "randomisation took place pre-operatively and the study nurse opened the envelope, informed the team of allocation and arranged the equipment if in intervention group". Comment: no mention of how envelopes were stored or whether they were numbered etc.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	On contact with authors, quote: "the women, the research nurse who collected the pain data from women, and the statistician were blinded. The physician could not be blinded. Blinding broken on women 7 days post- operatively."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research nurse who collected the pain data from women and the statistician were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts described
Selective reporting (reporting bias)	Low risk	Study authors report that all outcomes they set out to assess were reported
Other bias	Low risk	No other sources of bias identified

Liu 2014

Methods	<p>Study: single-centre RCT</p> <p>Country: China</p> <p>Type of surgery: diagnostic hysteroscopy and laparoscopy +/- tubal patency testing or tubal resection</p> <p>Number and type of laparoscopic ports: 12mm umbilical port x 1 and 5 mm ports x 3 in the lateral lower abdominal wall and suprapubic area</p> <p>Distention medium and pressures: CO₂ maintained at a pressure of 12 mmHg</p> <p>Study duration: 9 months</p> <p>Informed consent: yes</p> <p>Funding sources: not reported</p>
Participants	<p>60 women scheduled for diagnostic hysteroscopy and laparoscopy at the Department of Reproductive Medicine were randomised. 30 in intervention group (combined incisional ropivacaine and PRM) and 30 in control group (incisional infiltration of ropivacaine)</p> <p>Participants excluded: no women were excluded after randomisation</p> <p>Age (years, mean \pm SD): intervention 30.2 \pm 3.7, control 32.3 \pm 5.0</p> <p>BMI (kg/m², mean \pm SD): not reported</p>

Liu 2014 (Continued)

Ethnicity: not reported

Inclusion criteria

- Women aged 18-45 years
- Scheduled for diagnostic hysteroscopy and laparoscopy at the Department for Reproductive Medicine, Peking University Third Hospital

Exclusion criteria

- ASA ≥ 3
- Allergy or hypersensitivity to amide type local anaesthetics
- Contraindication to tramadol
- Pre-existing chronic pain disorders
- Receiving opioids or tranquillisers for > 1 week preoperatively
- History of drug or alcohol abuse
- Operation was converted to an open procedure, or had post-op complications that could increase post-op pain

Interventions	<p>Intervention: PRM. Woman placed in Trendelenburg position (30°), with 5 manual pulmonary inflations at a maximum pressure of 40 cm H₂O whilst the ports were open. The last inflation was held for 5 seconds.</p> <p>Control: routine method of gently pressing the abdominal wall to remove CO₂ through the 12 mm port.</p> <p>Both groups received 20 mL 0.5% ropivacaine peri-incisionally at the beginning of the operation</p>
Outcomes	<ul style="list-style-type: none"> • Incidence of STP within 48 h post-op • Analgesia requirements (unfortunately we were unable to use data from this outcome as the paper did not report the data) • Severity of STP on a numerical rating scale at 0, 2, 4, 8, 12, 24 and 48 h post-op (unfortunately data presented as graphs. Raw data not presented therefore unable to use in meta-analysis. Contacted study authors to request data but no response)
Notes	Authors contacted April 2017 for further data, but no response received.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Computer-generated random numbers"
Allocation concealment (selection bias)	Low risk	Quote: "Numbered and opaque envelopes opened by the surgeon upon women's arrival in the operating room"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Women and outcome assessors were blinded to the intervention." Comment: the surgeon could not be blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Women and outcome assessors were blinded to the intervention." Comment: the surgeon could not be blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts. All women randomised received the allocated intervention

Liu 2014 (Continued)

Selective reporting (re-reporting bias)	High risk	Analgesia requirement data were not reported in the paper. Data on STP, both incidence and severity, were not reported as means with SD as presented in the methods. STP was presented as "left and right" in the results, but splitting into laterality was not mentioned in the methods.
Other bias	Low risk	No other sources of bias identified

Loughney 1994

Methods	<p>Study: single-centre RCT</p> <p>Country: UK</p> <p>Type of surgery: diagnostic laparoscopy for investigation of intermittent pelvic pain or dyspareunia</p> <p>Number and type of laparoscopic ports: 1 x 1 cm subumbilical incision</p> <p>Distention medium and pressures: CO₂, pressure not described</p> <p>Study duration: not described</p> <p>Informed consent: not described</p> <p>Funding sources: none</p>
Participants	<p>47 women: 25 in the intervention group and 22 in the control group</p> <p>Participants excluded: 0</p> <p>Age (years, all women): only reports 18-55</p> <p>BMI (kg/m², mean ± SD): not described</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • ASA grade 1-2 • Diagnostic laparoscopy for investigation of intermittent pelvic pain or dyspareunia <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Not described
Interventions	<p>At the end of the procedure the abdomen "was deflated"</p> <p>Intervention: 17 mL of 0.25% bupivacaine was instilled into abdominal cavity via the umbilical port and a further 3 mL of 0.25% bupivacaine was then injected around the incision site</p> <p>Control: 17 mL sterile normal saline was instilled into abdominal cavity via the umbilical port and a further 3 mL normal saline was then injected around the incision site</p>
Outcomes	<ul style="list-style-type: none"> • Incidence of STP up to 3 days post-op. The only data on STP available in this paper are up to 4 h post-op • Severity of STP (unfortunately these data are a mixture of abdominal and STP and were captured via a verbal rating scale opposed to VAS as per our protocol, therefore data not used in meta-analysis) • Analgesia usage up to 4 h post-op (unfortunately analgesia usage was for both STP and abdominal pain and therefore not used in meta-analysis)
Notes	Attempted to contact authors January 2016 but no response

Loughney 1994 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Groups were allocated using a "computer-generated random number selector".
Allocation concealment (selection bias)	Unclear risk	None described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Group allocations were not revealed to the women, medical or nursing staff until completion of the trial." Comment: no other details are available.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessed by a combination of blinded nursing staff and self-reported questionnaires
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	40/47 women who were recruited returned their self-administered pain questionnaires from home
Selective reporting (reporting bias)	High risk	Did not fully report severity and site of STP from questionnaires self-administered at home, therefore we were unable to include data on incidence of STP up to 3 days post-op Dosage and timeframe of analgesia use was not reported.
Other bias	Low risk	No other sources of bias identified

Manwaring 2008

Methods	Study: single-centre RCT Country: Australia Type of surgery: gynaecological laparoscopy for endometriosis, adhesions or adnexal pathology Number and type of laparoscopic ports: 2-3 ports, size not described Distention medium and pressures: CO ₂ , 15 mmHg Study duration: 8 months Informed consent: yes Funding sources: none described but some equipment supplied by Fisher and Paykel Healthcare
Participants	60 women: 30 in intervention group and 30 in control group Participants excluded: none Age (years, mean \pm SD): control 30 \pm 9.0, intervention 30 \pm 7.2 BMI (kg/m ² , mean \pm SD): control 24 \pm 4.1, intervention 25 \pm 5.6 Ethnicity: not described

Manwaring 2008 (Continued)

Inclusion criteria

- Adequate grasp of English
- Ability to give informed consent
- Expected operative time between 30 and 90 min without major operative procedures such as colpotomy, myomectomy, or hysterectomy

Exclusion criteria

- If procedure lasted for > 90 minutes

Interventions	<p>Intervention: CO₂ warmed and humidified to 37°C and 100% relative humidity via a laparoscopic humidification system</p> <p>Control: "normal" insufflation CO₂ (room temp and dry)</p>
Outcomes	<ul style="list-style-type: none"> • Severity of STP using a VAS score (1-10) at 1, 2, 4 and 24 h post-op. All data from all time points obtained from J. Manwaring on request • Analgesia usage. It is unclear over what time period this was planned to be assessed. Unfortunately we were unable to use these data for that reason, and because it combined analgesia for STP and abdominal pain
Notes	We contacted study author, J Manwaring in January 2016, who provided information regarding the study that helped assess risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation occurred via random number generator with number sealed in sequential opaque envelopes"
Allocation concealment (selection bias)	Low risk	Quote: "Randomisation occurred via random number generator with number sealed in sequential opaque envelopes. Envelopes opened by nurse in theatre not associated with the study."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	<p>Study authors confirmed, quote: "women were blinded and that blinding was not broken until study completed."</p> <p>Comment: personnel could not be blinded owing to nature of intervention</p>
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Women and nursing staff who administered the VAS and analgesia were blinded"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing women
Selective reporting (reporting bias)	Low risk	<p>VAS scores at 1, 2 and 4 h were not reported individually, or according to site of pain in paper, but were obtained on written request to study authors.</p> <p>Additionally, data on patient experience of pain, doses of other analgesics used in recovery and other side effects post-op were collected but not published. These data were made available to us.</p>
Other bias	Low risk	No other sources of bias identified

Narchi 1991

Methods	<p>Study: RCT</p> <p>Country: France</p> <p>Type of surgery: diagnostic laparoscopy</p> <p>Number and type of laparoscopic ports: 1 port (size not described) inserted peri-umbilically, additional needle inserted into right lower quadrant, 23 cm long internal diameter 1.5 mm</p> <p>Distention medium and pressures: not described</p> <p>Study duration: not described</p> <p>Informed consent: not described</p> <p>Funding sources: not described</p>
Participants	<p>80 women, 20 randomised to intervention group A (saline), 20 randomised to intervention group B (lignocaine), 20 randomised to intervention group C (bupivacaine) and 20 randomised to group D (control)</p> <p>Participants excluded: 15 excluded; 6 didn't return questionnaires (group A = 2; group C = 3; group D = 1), 9 underwent laparoscopic excision of ovarian cysts (group A = 3; group C = 2; group D = 4)</p> <p>Age (years, mean \pm SD): group A: 32 \pm 5, group B: 33 \pm 3, group C: 34 \pm 5, group D: 29 \pm 3</p> <p>BMI (kg/m², mean \pm SD): not described</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> Women undergoing diagnostic laparoscopy for tubal infertility, chronic salpingitis or suspected endometriosis <p>Exclusion criteria</p> <ul style="list-style-type: none"> History of heart disease Previous laparotomy
Interventions	<p>Following initial insertion of the peri-umbilical trocar and laparoscope the participants were randomised into 1 of 4 groups;</p> <p>For the following 3 (intervention) groups, a 23 cm long needle with an internal diameter of 1.5 mm was inserted into the lower right quadrant of the abdomen and advanced over the anterior hepatic surface so that solution could be infiltrated into the right subdiaphragmatic area</p> <p>Intervention group A: 80 mL normal saline</p> <p>Intervention group B: 80 mL 0.5% lignocaine with adrenaline (320,000 dilution)</p> <p>Intervention group C: 80 mL 0.125% bupivacaine with adrenaline (800,000 dilution)</p> <p>Control group D: no fluid instilled</p>
Outcomes	<ul style="list-style-type: none"> Severity of STP using a VAS (0-10) at 6 time intervals; in the recovery room and "immediately before discharge from the unit" and then self-reported at 12, 24, 36, and 48 h post-op with a questionnaire posted back in a pre-stamped envelope. Analgesia usage from 12-28 h post-op (unfortunately these data were not reported and therefore could not be used)

Narchi 1991 (Continued)

Notes

In this study, groups A and D could both be considered control groups. For this study we chose group D to be the control as it didn't involve injecting the subdiaphragmatic space. Group A data have not been included in meta-analysis

We input data on side effects on an ITT basis. We split the control group between interventions on one forest plot for both adverse events and severity of STP.

We input continuous data on severity of STP on an available case analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Were randomly assigned" Comment: no other information
Allocation concealment (selection bias)	Unclear risk	No method described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Only comments were that the solutions used were "given double-blind". Control group (group 1) was not blinded to surgeon, patient or nurse
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessment, quote: "...questioned about their post-op pain by a nurse who was unaware of the study"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of 80 women recruited, 15 were not included; 9 women required "surgical resection of ovarian cysts" and 6 women failed to return the questionnaires. Original group allocations reported.
Selective reporting (reporting bias)	Low risk	No clear evidence of selective reporting
Other bias	Low risk	No other sources of bias identified

Ozer 2005

Methods

Study: RCT

Country: Turkey

Type of surgery: "minor" laparoscopic gynaecological surgery

Number and type of laparoscopic ports: 3 ports (size not described)

Distention medium and pressures: CO₂, pressure 13 mmHg

Study duration: not described

Informed consent: yes

Funding sources: not described

Participants

Participants: 56 women: 28 intervention, 28 control

Ozer 2005 (Continued)

Participants excluded: 5 in total (3 women - 1 in intervention group and 2 in control group) were excluded as they did not return the questionnaire. Another 2 women (1 in each group) were excluded because each received metoclopramide instead of ondansetron.

Age (years, mean): intervention: 38, control: 34

BMI (kg/m², mean \pm SD): not described

Ethnicity: not described

Inclusion criteria

- ASA 1-2
- Undergoing "minor" laparoscopic gynaecological surgery

Exclusion criteria

- Contraindications to meperidine, Metamizole or bupivacaine
- Receiving analgesic medication on a regular basis

Interventions	<p>At the end of the operation, the surgeon inserted an epidural catheter into the peritoneal cavity through an 18-G Tuohy needle 5–6 cm below the right costal margin in the mid-clavicular line. The tip of the epidural catheter was placed in the right subdiaphragmatic area with a forcep under laparoscopic control, and the pneumoperitoneum was ended.</p> <p>The solutions were instilled through the subphrenic catheter before incision closure and at 4-hourly intervals for the first post-op 20 h. The catheter was removed after the last dose and the women were discharged 4 h after</p> <p>Intervention: 20 mL of bupivacaine 0.125% plus epinephrine 1:200 000</p> <p>Control: 20 mL of normal saline plus epinephrine 1:200 000</p>
Outcomes	<ul style="list-style-type: none"> • Incidence of STP on days 2, 3, 4 and 7 post-op. We were only able to obtain accurate data for day 2 post-op as the proportion of women affected were provided in the text alongside a graph. The data from other time points are only displayed on a very small graph from which data cannot be accurately drawn • Severity of STP using VAS (0-10). Unfortunately we were unable to use these data as they were mixed with other sites of pain • Analgesic requirements. We were unable to use these data as analgesia requirements were not confined to STP only. • Adverse events
Notes	Authors contacted by email May 2017, but no response

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Women were randomised according to a table of random numbers."
Allocation concealment (selection bias)	Unclear risk	<p>Quote: "The allocations were kept in sealed envelopes",</p> <p>Comment: but no mention of whether they were numbers or opaque.</p> <p>Quote: "A physician who did not participate in any phase of the study had prepared six syringes of blinded solutions for each patient in a sterile fashion."</p>

Ozer 2005 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "A physician who did not participate in any phase of the study had prepared six syringes of blinded solutions for each patient in a sterile fashion." Comment: no explicit confirmation of participant or surgeon blinding but study described as "double-blind" and very strongly inferred that women and operator were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	A blinded investigator instructed women on self-administered questionnaires We strongly suspect women were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	All women accounted for. 51/56 randomised women completed the study. 3 women (1 in intervention group and 2 in control group) were excluded from the study, as they did not return the questionnaire. Another 2 women (one in each group) were excluded because each received metoclopramide instead of ondansetron
Selective reporting (reporting bias)	Unclear risk	All data mentioned in methods were presented, however, they were presented in a format that makes it difficult to extract for meta-analysis. No access to protocol or contact with study authors to confirm all outcomes assessed were published
Other bias	Low risk	No other sources of bias identified

Perry 1993

Methods	Study: multicentre RCT Country: USA Type of surgery: operative gynaecological laparoscopy Number and type of laparoscopic ports: not described Distention medium and pressures: CO ₂ , pressure not described Study duration: 15 months Informed consent: yes Funding sources: not described
Participants	137 women randomised: 68 in intervention and 69 in control Participants excluded: none Age (years, mean \pm SD): not described BMI (kg/m ² , mean \pm SD): not described Ethnicity: not described per group, but overall 134 women were described as white and 3 as black. Inclusion criteria <ul style="list-style-type: none"> Women undergoing operative laparoscopy in 2 private practices Exclusion criteria <ul style="list-style-type: none"> Women undergoing laparoscopic hysterectomy

Perry 1993 (Continued)

Interventions	<p>Intervention: 1-2 Lof normal saline or Ringer's lactate instilled into the abdominal cavity as the CO₂ was released</p> <p>Control: no fluid instillation, but expulsion of pneumoperitoneum was emphasised</p>
Outcomes	<ul style="list-style-type: none"> Severity of STP on a numerical rating scale. Unfortunately these data are not usable as they are combined with "pain in sub diaphragm and neck" alongside STP Incidence of STP. Unfortunately these data are not usable as the study authors assessed incidence in relation to posture (standing or lying prone). Additionally, STP was reported as "no pain" if it was "absent or reduced".
Notes	This is an old study with no up to date contact details for the authors. We did not use any data for meta-analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Random number tables were used for group assignment."
Allocation concealment (selection bias)	Low risk	Quote: "Numbered opaque envelopes"
Blinding of participants and personnel (performance bias) All outcomes	High risk	<p>Quote: "It was impossible to completely blind women regarding fluid instillation since incisional leakage occurs normally."</p> <p>Comment: blinding appears to have been broken in women. It was impossible to blind the surgeon.</p>
Blinding of outcome assessment (detection bias) All outcomes	High risk	Nursing personnel calling women to obtain pain scale were blind to patient allocation, however women were not blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts
Selective reporting (reporting bias)	High risk	Data on severity of STP are not available for all women included in the study
Other bias	Low risk	No other sources of bias identified

Phelps 2008

Methods	<p>Study: multicentre RCT</p> <p>Country: USA</p> <p>Type of surgery: elective gynaecological surgery including: diagnostic laparoscopy, tubal ligation, ovarian cystectomy, salpingo-oophorectomy, fulguration of endometriosis, oophorectomy and umbilical hernia repair</p> <p>Number and type of laparoscopic ports: 2-3 ports, 1 umbilically (5-10 mm) and further 1 or 2 ports (5 mm)</p> <p>Distention medium and pressures: CO₂, 15 mmHg</p>
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Phelps 2008 (Continued)

Study duration: 24 months

Informed consent: yes

Funding sources: none described

Participants	<p>Participants: 116 women randomised: 61 in intervention group and 55 in control group</p> <p>Participants excluded: 17 women were excluded. 7 from intervention group: 2 were converted to laparotomy; 1 admitted for medical reasons, 3 did not return the questionnaire and 1 had no consent form. 9 women were excluded from the control group: 1 converted to dilation and curettage, 4 were converted to laparotomy and 4 did not return their questionnaire.</p> <p>Age (years, mean \pm SD): intervention: 33.8 \pm 0.9, control: 35.0 \pm 1.17</p> <p>BMI (kg/m², mean \pm SD): intervention: 25.6 \pm 0.8, control: 26.6 \pm 0.8</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • ASA 1-2 • Age 15-65 years • No history of previous laparotomy <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Required hospitalisation after the laparoscopic surgery • The procedure required conversion to laparotomy • 48-h follow-up was not feasible
Interventions	<p>Intervention: in Trendelenberg position (30°), a PRM consisting of 5 manual pulmonary inflations was performed with a maximum pressure of 60 cm H₂O. The anaesthetist held the 5th positive pressure inflation for approximately 5 s. During these manoeuvres, the surgeon was instructed to ensure that the trocar sleeve valve was fully open to allow the CO₂ gas to escape.</p> <p>Control: CO₂ was removed by passive exsufflation through the port site. Gentle abdominal pressure was applied to evacuate as much gas as possible.</p>
Outcomes	<ul style="list-style-type: none"> • Severity of STP using a VAS score (0-100) before discharge and then at 12, 24, 36, and 48 h following discharge. Unfortunately data from immediately before discharge and 48 h post-op are not published numerically in the text of the paper, only as graphs, which we cannot extract data from. Data presented as means and standard error of the mean (SE). We converted SE to SD for this review. • Incidence of STP within 48 h post-op • Adverse events. Unfortunately we cannot use these data as the study does not report adverse events for control arm in same way as it does for intervention arm.
Notes	<p>Note that one woman in the intervention arm underwent a non-gynae operation (umbilical hernia repair)</p> <p>Data on incidence of STP utilised on an ITT basis</p> <p>Continuous data on severity of STP input on available case analysis</p> <p>VAS score and SD converted from 0-100 to 0-10 for purposes of inputting data into this review</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
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Phelps 2008 (Continued)

Random sequence generation (selection bias)	Low risk	Quote: "Sealed envelopes which were manually shuffled and inserted into numbered envelopes were used"
Allocation concealment (selection bias)	Low risk	Quote: "A single envelope was opened directly <i>before</i> the operation by the anaesthetist. Only the anaesthetist for the specific case was aware of the treatment allocation until the end of the surgical procedure when either the intervention or the control manoeuvre was performed."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The patient, post-anaesthesia care unit staff and the investigator obtaining post-op scores were blinded to the women group allocation. The investigator who assessed the outcomes was not present in the operating room during the intervention."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Women were blinded and it was a self-administered questionnaire
Incomplete outcome data (attrition bias) All outcomes	Low risk	Clear flowchart for group allocation. Attrition/exclusions reported and described
Selective reporting (reporting bias)	High risk	No access to study protocol. Attempted to contact study authors to confirm all outcomes published, but no response. Reporting of adverse events was not mentioned in the methods other than nausea and vomiting. However, in the results there is mention of "no cardiovascular or pulmonary complications as a result of the manoeuvre." Additionally, the mention of serious surgical complications (bowel and bladder injury) not related to the manoeuvre are mentioned, but not per randomised group. Therefore these data are unusable in meta-analysis. This may represent reporting bias. Outcomes for severity of STP at discharge and 48 h not published numerically in text as per other time points, presumably because of non statistical significance (judging by graph).
Other bias	Unclear risk	Note that one woman in the intervention arm underwent a non-gynae operation (umbilical hernia repair)

Radosa 2013

Methods	<p>Study: single-centre RCT</p> <p>Country: Germany</p> <p>Type of surgery: laparoscopic hysterectomy for benign conditions (TLH and LASH)</p> <p>Number and type of laparoscopic ports: 4 ports; 10 mm umbilical x 1, 3 mm in inferolateral abdominal wall x 2, and 3 mm in suprapubic area x 1</p> <p>Distention medium and pressures: CO₂ to 20 mmHg until ports were sited, then pressure reduced to 14 mmHg with a flow rate of ≤ 3 L/min</p> <p>Study duration: 41 months</p> <p>Informed consent: yes</p> <p>Funding sources: none</p>
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Radosa 2013 (Continued)

Participants	<p>A total of 293 women randomised: 998 in intervention group A (EAV), 95 in intervention group B (EAV and TSI), and 6 in control group</p> <p>Participants excluded: 4 women were excluded from the study: 2 from intervention group A, 1 from intervention group B and 1 from the control group. None of the 4 women completed the post-op questionnaire. 2 were Clavien-Dindo grade 3 post-op complications and the other 2 were discharged from the hospital within 24 h post-op</p> <p>Age (years, mean \pm SD all women): 45.44 \pm 7.55</p> <p>BMI (kg/m², mean \pm SD all women): 26.72 \pm 6.1 kg/m²</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • Age 30-70 years • Hysterectomy indicated for a benign gynaecological condition • ASA physical status classification of 1-2 <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Refusal to participate in the study • Severe intraoperative complications, defined as bowel, bladder or ureteric injury, major bleeding requiring intraoperative or post-op transfusion, and/or pronounced subcutaneous emphysema • Unintended conversion from laparoscopy to laparotomy or abandonment of the intended surgical procedure • Lack of 48-h post-op follow-up • Inability to obtain post-op data due to post-op Clavien-Dindo grade 3-5 post-op complications
Interventions	<p>Intervention group A (EAV): umbilical valve was left open after working trocar removal and abdominal compression. The participant was placed in an anti-Trendelenburg position and received assisted ventilation for an additional 5 min. Ventilation was pressure controlled. Participant was then moved into a horizontal position and the umbilical optic trocar was removed under visual control</p> <p>Intervention group B (EAV and TSI): as per the EAV group plus the umbilical and working trocar incisions were each infiltrated with 5 mL 0.4% lidocaine hydrochloride after optic trocar removal</p> <p>Control group: the two 3 mm working trocars were removed under visual control. The umbilical optic trocar valve was opened and the abdominal wall was compressed to remove residual CO₂, then the optic trocar was removed under direct visual control</p> <p>In all groups, an 18 French gauge intra-abdominal drain was sited through one of the 3 mm port sites for post-op monitoring</p>
Outcomes	<ul style="list-style-type: none"> • Severity of STP using NRS (range 0-10) at 3, 24 and 48 h post-op • Analgesia requirements (expressed as mean post-op piritramide dose in milligrams per participant) at 3 h and 24 h post-op. • Adverse events
Notes	ITT analysis of data
Risk of bias	
Bias	Authors' judgement Support for judgement
Random sequence generation (selection bias)	<p>Low risk</p> <p>Quote: "All study women were assigned randomly to study groups (control, EAV, EAV & TSI) using a computer-generated randomisation list."</p>

Radosa 2013 (Continued)

Allocation concealment (selection bias)	Low risk	From correspondence with study author, quote: "The randomisation list was held by the principal investigator who did not see women in clinic. Clinicians had to call the principle investigator to establish the allocation of the patient"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	From correspondence with study author, quote: "patients were blinded and did not know which treatment group they were assigned. Analgesia was provided by the clinician on duty who was not part of the study personnel and did not know which group the patient was allocated to"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	From correspondence with study author: "Pain score questionnaires were administered by the nurses on the ward who were not part of the study personnel and did not know of the patient allocation group"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons for excluded women clearly stated and comply with stated exclusion criteria
Selective reporting (reporting bias)	Low risk	From correspondence with study author: "All outcomes have been published"
Other bias	Low risk	No other sources of bias identified

Roy 2014

Methods	<p>Study: single-centre RCT</p> <p>Country: India</p> <p>Type of surgery: diagnostic mini-laparoscopy and tubal patency testing</p> <p>Number and type of laparoscopic ports: 2 ports; 3 mm subumbilical x 1, lateral 3 mm port x 1</p> <p>Distention medium and pressures: CO₂, pressure not reported</p> <p>Study duration: 12 months</p> <p>Informed consent: yes</p> <p>Funding sources: not reported</p>
Participants	<p>110 infertile women undergoing diagnostic mini-laparoscopy were randomised: 55 in intervention group, 55 in control group</p> <p>Participants excluded: 2 women from the intervention group and 4 women from the control group were excluded. The 6 excluded women all received an operative intervention which was deemed an exclusion criterion</p> <p>Age (years, mean \pm SD): intervention: 28.4 \pm 4.6, control: 29.3 \pm 2.9</p> <p>BMI (kg/m², mean \pm SD): intervention: 23.1 \pm 1.2, control: 24 \pm 1.4</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • Women with infertility • Negative urinary pregnancy test • Signed informed consent • ASA physical status classification of 1-2

Roy 2014 (Continued)

Exclusion criteria

- Allergy to bupivacaine
- Need for an operative procedure
- Acute cervicitis
- Chronic pain syndrome

Interventions	Intervention: 10 mL of intraperitoneal 0.25% bupivacaine Control: 10 mL of intraperitoneal normal saline
Outcomes	<ul style="list-style-type: none"> • Incidence of STP within 8 h post-op • Analgesia requirements. Unfortunately we are unable to use these data in meta-analysis as type and dose of analgesia not described, only incidence of use. Additionally, analgesia use was for combination of sources of pain which included abdominal as well as STP. Contacted study authors April 2017 for further information, but no response
Notes	<p>Emailed study authors April 2017 for further information, but no response</p> <p>Location within abdomen of placement of intraperitoneal bupivacaine or saline is not documented in paper</p> <p>Data on incidence of STP input on ITT basis</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Computer-generated random numbers"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "A resident who was not involved in the actual procedure prepared the medication as 10 mL of unlabelled solution, therefore both women and gynaecologist were blinded to the intervention."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Assessments carried out by residents blinded to intervention."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Dropouts accounted for as per study protocol
Selective reporting (reporting bias)	Unclear risk	No access to protocol to establish if all outcomes reported
Other bias	Low risk	No other sources of bias identified

Sharami 2010

Methods	Study: single-centre RCT Country: Iran
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Sharami 2010 (Continued)

Type of surgery: minor laparoscopic gynaecological surgery, including diagnostic laparoscopy, ovarian cystectomy, tubal ligation, ectopic pregnancy, cauterisation of polycystic ovaries and adhesiolysis

Number and type of laparoscopic ports: 10 mm umbilical port, another 1-2 ports if required, size not clarified

Distention medium and pressures: CO₂, 15 mmHg

Study duration: 10 months

Informed consent: yes

Funding sources: none outlined

Participants	<p>146 women randomised: 75 in intervention group and 71 in control group</p> <p>Participants excluded: 15 women were excluded from the final analysis (8 from intervention group and 7 from control group) : 5 cases were converted to laparotomy (4 in intervention and 1 in control group); 7 cases because of intra-abdominal pressure exceeding 15 mmHg (3 in intervention group; 4 in control); 2 women needed concomitant surgery (both in control group) and 1 had an incomplete data set (intervention group)</p> <p>Age (years, mean ± SD): intervention 29 ± 6.1, control; 27.37 ± 6.0</p> <p>BMI (kg/m², mean ± SD): intervention 26.88 ± 4.0, control: 25.97 ± 4.9</p> <p>Ethnicity: not reported</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • Undergoing minor laparoscopic gynaecological surgery • Aged 15-50 years • "Communicability" • No history of laparotomy • ASA physical status classification 1-2 <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Intra-abdominal pressure exceeded 15 mmHg during the operation • Concomitant non-laparoscopic surgery • Conversion to laparotomy • Lost to follow-up
Interventions	<p>Intervention: at the end of the procedure, "the women were placed in the Trendelenburg (30°) position and manual pulmonary inflation was performed with a positive pressure of 40 cmH₂O, five times." Last inhalation held for 5 s and gentle abdominal pressure by the surgeon.</p> <p>Control: at the end of the procedure, "the abdomen was compressed by the surgeon to facilitate gas removal as much as possible"</p>
Outcomes	<ul style="list-style-type: none"> • Incidence of STP at 4, 12, 24 and 48 h. We obtained these data on communication with study author and utilised data in meta-analysis from overall incidence of STP over 48-h period • Severity of STP using VAS (0-10cm) at 4, 12, 24 and 48 h post-op • Analgesic requirements (100 mg diclofenac suppositories). We calculated means and SDs from data provided by the study authors • Adverse events
Notes	<p>Contacted study authors May 2017 for clarification on data. Data obtained on incidence of STP and analgesia usage used in this review</p>

Sharami 2010 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Subjects were randomly assigned to receive manual pulmonary inflations or not, using computer-generated randomisation blocks, stratified for procedure"
Allocation concealment (selection bias)	Low risk	Quote: "Concealment was achieved by the allocation being placed in opaque envelopes. A single envelope was opened by the anaesthetist before the operation"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Neither the women nor the resident knew the group assignment. Blinding was maintained throughout the procedure and follow-up" Comment: surgeon and anaesthetist were aware of the allocation before the operation started
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Data collection was carried out by a gynaecological resident. Neither the patients nor the resident knew the group assignment. Blinding was maintained throughout the procedure and follow-up."
Incomplete outcome data (attrition bias) All outcomes	Low risk	All attrition/exclusions accounted for
Selective reporting (reporting bias)	Low risk	Did not report data on incidence of STP at all time points per randomised group in paper, but study authors happily disclosed these data on request
Other bias	High risk	Mean duration of surgery and total volume of CO ₂ significantly less in the intervention group.

Shen 2003

Methods	<p>Study: single-centre RCT</p> <p>Country: Taiwan</p> <p>Type of surgery: LAVH for fibroids, adenomyosis, endometriosis, cervical intraepithelial neoplasia, menorrhagia and endometrial hyperplasia</p> <p>Number and type of laparoscopic ports: not described</p> <p>Distention medium and pressures: CO₂ 15 mmHg</p> <p>Study duration: not described</p> <p>Informed consent: not described</p> <p>Funding sources: none described</p>
Participants	<p>Participants: 175 women undergoing LAVH. Of these women 11 were excluded after randomisation leaving 164 women: 80 in intervention group and 84 in control group</p> <p>Participants excluded: 11 women excluded because of conversion to laparotomy (study group not stated)</p> <p>Age (years, mean \pm SD): intervention 44.2 \pm 6.2, control; 44.0 \pm 6.3</p>

Shen 2003 (Continued)

BMI (kg/m², mean \pm SD): intervention: 22.0 \pm 3.0, control: 22.4 \pm 3.3

Ethnicity: not described

Inclusion criteria

- Women undergoing LAVH

Exclusion criteria

- History of pelvic inflammatory disease
- Allergy to cephalothin or gentamicin
- History of pre-operative shoulder, abdominal or back pain
- Conversion to laparotomy
- Women with endometriosis associated with pre-operative abdominal and back pain

Interventions	<p>Intervention: closed suction drain inserted into pelvis ("cul-de-sac") via right suprapubic port at end of standard procedure. It is not clear at what time point post-op the drain was removed.</p> <p>Control: no drain</p>
Outcomes	<ul style="list-style-type: none"> • Severity of STP using VAS (0-10 cm) at 3, 24 and 48 h post-op • Incidence of STP • Analgesia usage (mean paracetamol tablets used \pm SD) • Adverse events

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Computer-generated randomisation code"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Clinicians and women not blinded."
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Self-reported VAS scores" Comment: women not blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	11 women were excluded following randomisation
Selective reporting (reporting bias)	Unclear risk	No access to protocol
Other bias	Low risk	No other sources of bias identified

Suginami 2009

Methods	<p>Study: single-centre RCT</p> <p>Country: Japan</p> <p>Type of surgery: any gynaecological laparoscopic surgery including endometriosis, hysterectomy, myomectomy and ovarian cystectomy</p> <p>Number and type of laparoscopic ports: 15 mm subumbilical incision, 5 mm lateral ports x 2</p> <p>Distention medium and pressures: CO₂, 8 mmHg</p> <p>Study duration: not described</p> <p>Informed consent: yes</p> <p>Funding sources: none described</p>	
Participants	<p>Participants: 40 women: 21 in intervention group, 19 in control group</p> <p>Participants excluded: none</p> <p>Age (years, mean ± SD): intervention: 39.0 ± 7.3, control: 39.0 ± 6.8</p> <p>BMI (kg/m², mean ± SD): not described</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none">• All consecutive women undergoing laparoscopic gynaecological surgery <p>Exclusion criteria</p> <ul style="list-style-type: none">• None described	
Interventions	<p>Intervention: "Warm saline instilled into the abdomen through one of the 2 suprainguinal ports until it spilled out of the remaining open trocars. The amount of saline pumped in ranged from 1000 mL to 1500 mL". (In Trendelenberg). Wound sites were then closed.</p> <p>Control: "on completion of the procedure the trocars were opened and abdominal pressure by the surgeon's hands to evacuate the residual CO₂" (In Trendelenberg). Wound sites were then closed.</p>	
Outcomes	<ul style="list-style-type: none">• Severity of STP using VAS scores (score not described) twice daily (am and pm) until day 3 post-op. Unfortunately we were unable to extract data from this paper as the mean VAS scores are displayed on a small graph with standard errors of mean incalculable.• Adverse events	
Notes	Contacted study authors May 2017 for data, but no response	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Consecutive women, quote: “were randomly enrolled in either one of the following 2 groups...”. Comment: unsure exactly how this was achieved
Allocation concealment (selection bias)	Unclear risk	None described

Suginami 2009 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "They were not informed of their grouping." Comment: however, it is possible that women in the intervention group would be aware of their allocation group because of increased port site 'leakage' of instilled fluid. Comment: no evidence of other personnel being blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Nurses blinded to the participant's grouping recorded shoulder pain VAS scores. However, given nature of intervention, blinding would have been very difficult given the amount of leaking of fluid that would have occurred via the port sites. Women were likely to have their blinding broken.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The paper does not mention any exclusions/attrition, but 3 days of data are available. It is uncommon for women to stay in 3 full days post-op following a gynaecology laparoscopy. Therefore perhaps women went home with a VAS score? Attrition from self-recorded questionnaires at home is common.
Selective reporting (reporting bias)	Unclear risk	Unable to confirm given no access to protocol and unable to contact study authors
Other bias	Low risk	No other sources of bias identified

Sutchritpongsa 2013

Methods	<p>Study: single-centre RCT</p> <p>Country: Thailand</p> <p>Type of surgery: elective laparoscopic surgery for gynaecological problems including TLH, myomectomy, salpingo-oophorectomy, ovarian cystectomy, salpingectomy and adhesiolysis, performed by 4 laparoscopic surgeons</p> <p>Number and type of laparoscopic ports: not described</p> <p>Distention medium and pressures: not described</p> <p>Study duration: 6 months</p> <p>Informed consent: yes</p> <p>Funding sources: not described</p>
Participants	<p>158 women randomised: 79 in intervention group, 79 in control group</p> <p>Participants excluded: none described</p> <p>Age (years, mean \pm SD): intervention group: 42.2 \pm 10.2, control group: 39.5 \pm 8.6</p> <p>BMI (kg/m², mean \pm SD): intervention group: 21.5 \pm 3.0, control group: 22.6 \pm 4.2</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> Female ASA physical status classification of 1-2 Undergoing elective gynaecological laparoscopic surgery <p>Exclusion criteria</p>

Sutchritpongsa 2013 (Continued)

- Undergoing emergency gynaecological laparoscopic surgery
- Contraindications to local anaesthetic, opioids and sulphonamides
- Medical history of asthma, hepato-renal and cardiovascular disease
- Conversion from laparoscopy to laparotomy
- Operating time > 3 h

Interventions	<p>Intervention: 20 mL of 0.5% bupivacaine hydrochloride plus 3 mg morphine was injected intraperitoneally into both subdiaphragmatic surfaces by using a long laparoscopic needle injection instrument (Karl-Storz, Germany) under direct vision with the participant in deep Trendelenburg position. CO₂ gas was removed manually from the woman's abdomen as much as possible before removing the trocars.</p> <p>Control: 20.3 mL normal saline was injected intraperitoneally into both subdiaphragmatic surfaces by using a long laparoscopic needle injection instrument (Karl-Storz, Germany) under direct vision with the participant in deep Trendelenburg position. CO₂ gas was removed manually from the woman's abdomen as much as possible before removing the trocars.</p>
Outcomes	<ul style="list-style-type: none"> • Severity of STP using a NRS (0-10) immediately, at 12 h and 24 h post-op. Unfortunately we have been unable to use these data in meta-analysis as they are presented as medians with IQRs • Analgesia usage for STP (paracetamol or pethidine) within 24 h post-op. Unfortunately we have been unable to use these data in meta-analysis as they are presented as medians with IQRs • Incidence of STP immediately, at 12 h and 24 h post-op • Adverse events related to intervention. Unfortunately we were unable to use this data as the study authors do not publish which arm of the study experienced the adverse event
Notes	<p>Study authors contacted April 2015 but no response received</p> <p>Data for incidence of STP at 24 h used in meta-analysis. Cannot use 12 h scores as well in same meta-analysis. No response from study authors when requested combined incidence over 24 h.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The patients were randomly allocated to one of the two groups" Comment: the study authors used computerised random allocation
Allocation concealment (selection bias)	Unclear risk	None described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unknown whether women were blinded, but it is likely that they were, given that blinding of the surgeon is described.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Self-administered VAS scores and women were probably blinded, but this is not confirmed
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unknown whether there were any dropouts or exclusions
Selective reporting (reporting bias)	High risk	No reporting of STP incidence/VAS immediately post-op No reporting of which arm of the trial suffered the "minor eczematous rash" which may have been a drug reaction as authors go on to write "no other adverse drug effect was seen".

Sutchritpongsa 2013 (Continued)

Other bias	Low risk	No other sources of bias identified
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Sutchritpongsa 2015

Methods	<p>Study: single-centre RCT</p> <p>Country: Thailand</p> <p>Type of surgery: elective laparoscopic gynaecological surgery</p> <p>Number and type of laparoscopic ports: not described</p> <p>Distention medium and pressures: not described</p> <p>Study duration: 11 months</p> <p>Informed consent: not described</p> <p>Funding sources: not described</p>
Participants	<p>160 women were randomised: 80 in intervention group, 80 in control group</p> <p>Participants excluded: not described</p> <p>Age (years, mean \pm SD): not described</p> <p>BMI (kg/m², mean \pm SD): not described</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> Undergoing elective gynaecological laparoscopic surgery ASA physical status classification of 1-2 <p>Exclusion criteria</p> <ul style="list-style-type: none"> Not described
Interventions	<p>Intervention: routine abdominal compression followed by the PRM. PRM was performed by the anaesthetist who undertook 5 manual pulmonary inflation breaths with a positive pressure of 40 cm H₂O. The last inflation was held for 5 s. The trocar sleeve was open to allow gas to escape</p> <p>Control: routine abdominal compression by the surgeon at the end of the operation to expel as much gas as possible</p>
Outcomes	<ul style="list-style-type: none"> Incidence of STP within 24 h post-op Analgesic requirements (unable to use data in meta-analysis as presented as ranges only) Severity of STP (unable to use data in meta-analysis as presented as ranges only)
Notes	Contacted study authors April 2015 and May 2017. No response

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described

Sutchritpongsa 2015 (Continued)

Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not described
Selective reporting (reporting bias)	High risk	Paper is an abstract, never went on to be fully published as far as we can tell (note: intervention revealed evidence of no improvement in pain). No access to study authors or protocol to establish whether all outcomes were published.
Other bias	Low risk	No other sources of bias identified

Swift 2002

Methods	<p>Study: multicentre RCT</p> <p>Country: Australia</p> <p>Type of surgery: diagnostic or operative laparoscopic gynaecological procedures for benign disease, including: resection of endometriosis; adhesiolysis; ovarian cystectomy, LAVH, colposuspension</p> <p>Number and type of laparoscopic ports: not described</p> <p>Distention medium and pressures: not described</p> <p>Study duration: not described</p> <p>Informed consent: yes</p> <p>Funding sources: funding source not disclosed, but MD Solutions, which is a medical devices company supplied the gas drains</p>
Participants	<p>80 women: 40 in intervention group and 40 in control group</p> <p>Participants excluded: 3 women from the intervention group dropped out, and were described as being "unable to be evaluated". 10 women from the control group dropped out because they failed to return their questionnaire.</p> <p>Age (years, mean \pm SD all women): intervention: 38.0 \pm 11.3, control: 32.7 \pm 8.5</p> <p>BMI (kg/m², mean \pm SD): not described</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> Any woman under the care of consultants involved in this study who were undergoing a diagnostic or operative laparoscopy

Swift 2002 (Continued)

Exclusion criteria

- Could not understand English satisfactorily
- A formal drainage system was deemed necessary intra-operatively

Interventions	<p>Intervention: a patent, colour-coded, intra-abdominal gas drain inserted via the umbilical port to a depth of 10 cm, removed at 4 h post-op</p> <p>Control: an occluded, colour-coded, intra-abdominal gas drain inserted via the umbilical port to a depth of 10 cm, removed at 4 h post-op. The 'blockage' was contained in an opaque connecting link.</p>
Outcomes	<ul style="list-style-type: none"> • Severity of STP using VAS score (0-10 cm) at 4, 12, 24, 48, 72, 96 and 120 h
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote: "Computer-generated random sequence".</p> <p>On contact with study author, quote: "Prior to the start of the study we produced (using a computerised random number generator) a list of numbers between 0 & 1. These were then converted to a colour (yellow & blue). The company producing the gas drains (blocked vs patent) then assigned the colours to the 2 groups & supplied the drains (with us the end-users blinded) as colour coded. The colour-coded assignment sheets were in opaque sequentially numbered sealed envelopes."</p>
Allocation concealment (selection bias)	Low risk	The colour-coded assignment sheets were in opaque, sequentially numbered, sealed envelopes. The colour-code key was kept blinded until the data analysis was completed.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The investigators, nursing staff and women were blinded as to whether the drain was patent or occluded."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Self-completed VAS scores and women were blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High attrition rate (13/80 women recruited) and 10 were from the control arm of the study. This led to slightly uneven numbers of participants in each arm. Unknown whether intervention linked to failure to return questionnaires.
Selective reporting (reporting bias)	Low risk	On contact with study author, it was revealed that all outcomes were published
Other bias	High risk	The control and intervention arms were unbalanced in terms of the operations they received. There was a wide variation in the complexity and therefore likelihood of post-operative pain in the control and intervention arm, with more complex operations in the control group. For example, there were 7 hysterectomies in the control group, and none in the intervention group.

Tsai 2011

Methods	<p>Study: single-centre RCT</p> <p>Country: Taiwan</p> <p>Type of surgery: laparoscopic surgery for benign gynaecological problem including LAVH, myomectomy and ovarian cystectomy</p> <p>Number and type of laparoscopic ports: 4 ports; 12mm umbilical x 1, 5 mm in lateral lower abdominal wall x 2, and 5 mm in suprapubic area x 1</p> <p>Distention medium and pressures: the CO₂ gas pressure was set at 15 mmHg during the procedure. The flow rate of CO₂ did not exceed 2L/min</p> <p>Study duration: 11 months</p> <p>Informed consent: yes</p> <p>Funding sources: declared and detailed as from the Taipei Veterans General Hospital and from the Yen-Tjing-Ling Medical Foundation</p>
Participants	<p>177 women randomised: 59 to each group. However, 19 women were withdrawn from the study leaving 53 in intervention group A (PRM), 54 in intervention group B (intraperitoneal normal saline infusion (INSI)), and 51 in the control group</p> <p>Participants excluded: 13 did not complete the post-op pain questionnaire, 5 were converted to laparotomy and 1 cancelled their surgery for personal reasons.</p> <p>Age (years, mean \pm SD): intervention group A (PRM) 42.1 \pm 8.1, intervention group B (INSI) 43.8 \pm 10.1, control group: 41 \pm 8.1</p> <p>BMI (kg/m², mean \pm SD all women): not provided</p> <p>Ethnicity: not described</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> Female Aged 24-65 years ASA physical status classification of 1-2 <p>Exclusion criteria</p> <ul style="list-style-type: none"> Not described
Interventions	<p>Intervention group A (PRM): women were placed in the Trendelenburg position and a PRM consisting of 5 manual pulmonary inflations was performed with a maximal pressure of 60 cm H₂O. The 5th positive pressure inflation was held for 5 s. During these inflations, the trocar sleeve valve was fully open allowing CO₂ to escape the abdominal cavity. Routine closure of port-sites then took place.</p> <p>Intervention group B (INSI): the upper part of the abdominal cavity was filled evenly and bilaterally with isotonic normal saline (15-30 mL/kg body weight) and left inside the abdominal cavity. During the procedure, the port sleeve valve was opened to allow CO₂ to escape the abdominal cavity. The women was then placed back in the level position, and routine port removal and abdominal closure took place.</p> <p>Control group: routine gentle abdominal pressure aiding removal of CO₂ by passive exsufflation through the port site at the end of surgery</p>
Outcomes	<ul style="list-style-type: none"> Severity of STP using a VAS (0-10 cm) at 12, 24 and 48 h post-op Incidence of STP at 12, 24 and 48 h post-op. Data input using ITT Analgesia usage measured as mean intravenous meperidine requirement (in milligrams) given per woman in the 48 h post-op

Tsai 2011 (Continued)

- Adverse events

Notes	NSAIDs were not used in the 48 h after the operation	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was achieved using a computerised, balanced 1:1:1 method."
Allocation concealment (selection bias)	Low risk	Quote: "The randomisation code was inserted into numbered, sealed, opaque envelopes however the surgeon performing the operation opened the envelope."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Study co-ordinators, women, gynaecologists, anaesthetists and members of the panel were not blinded to the intervention after randomisation, therefore no blinding took place
Blinding of outcome assessment (detection bias) All outcomes	High risk	Assessors and women were not blinded to the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	19 women were withdrawn from the study, however dropouts accounted for with legitimate reasons cited
Selective reporting (reporting bias)	Unclear risk	No access to protocol and no contact with study authors to clarify
Other bias	Low risk	No other sources of bias identified

Tsai 2013

Methods	<p>Study: single-centre RCT</p> <p>Country: Taiwan</p> <p>Type of surgery: laparoscopic surgery for benign gynaecological problems including LAVH, myomectomy and ovarian cystectomy</p> <p>Number and type of laparoscopic ports: 4 ports; 12 mm umbilical x 1, 5 mm in lateral lower abdominal wall x 2 and 5 mm in suprapubic area x 1</p> <p>Distention medium and pressures: the CO₂ gas pressure was set at 15 mmHg during the procedure. The flow rate of CO₂ did not exceed 2L/min</p> <p>Study duration: 11 months</p> <p>Informed consent: unknown</p> <p>Funding sources: not declared</p>
Participants	<p>102 women randomised: 50 in intervention group, 52 in control group</p> <p>Participants excluded: 2 women excluded from the study: both from the control arm. Both women had their laparoscopy converted to laparotomy because of severe adhesions</p>

Tsai 2013 (Continued)

Age (years, mean \pm SD): intervention group: 39.7 \pm 9.04, control group: 38.9 \pm 8.46

BMI (kg/m², mean \pm SD): intervention group: 22.7 \pm 3.94, control group: 22.6 \pm 3.98

Ethnicity: not described

Inclusion criteria

- Female
- Aged 20-65 years
- ASA physical status classification of 1-2
- Willingness to undergo laparoscopic surgery for benign gynaecological lesion

Exclusion criteria

- Malignant disease
- Unwilling to participate

Interventions	Intervention group: the upper part of the abdominal cavity was filled evenly and bilaterally with isotonic normal saline (15-20 mL/kg body weight) and left inside the abdominal cavity. The woman was then placed in the Trendelenburg position (30°) and the anaesthetist performed 5 manual pulmonary inflations at a maximum pressure of 60 cm H ₂ O. During the procedure, the port sleeve valve was opened to allow CO ₂ to escape the abdominal cavity. The woman was then placed back in the level position, and routine port removal and abdominal closure took place Control group: routine gentle abdominal pressure aiding removal of CO ₂ by passive exsufflation through the port site at the end of surgery	
Outcomes	<ul style="list-style-type: none">• Severity of STP using a VAS (0-10) at 12, 24 and 48 h post-op• Incidence of STP at 12, 24 and 48 h post-op. Data input on an ITT basis• Analgesia usage measured as mean intravenous meperidine requirement (in milligrams) given per woman in the 48 h post-op• Adverse events	
Notes	NSAIDs were not used in the 48 h after the operation	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was performed using a computerised balanced 1:1 method."
Allocation concealment (selection bias)	Low risk	Quote: "The randomisation code was inserted into numbered, opaque envelopes, however the surgeon performing the operation opened the envelope."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Surgeons and anaesthetists were not masked to the intervention, but the patient and post-op care unit staff were." Comment: it would be impossible to blind the surgeon and other operating theatre staff to the intervention, and should not have made a difference to the patient reported outcomes, so we consider this low risk
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The investigator obtaining post-op pain scores was blinded to group allocation. The women were blinded.

Tsai 2013 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	The dropouts were accounted for and were small in number.
Selective reporting (reporting bias)	Unclear risk	No access to protocol and no contact with study authors to clarify
Other bias	Low risk	No other sources of bias identified

ASA: American Society of Anesthesiologists; **EAV:** extended assisted ventilation; **IQR:** interquartile range; **ITT:** intention-to-treat (analysis); **LASH:** laparoscopic subtotal hysterectomy; **LAVH:** laparoscopically assisted vaginal hysterectomy; **NRS:** numeric rating scale; **NSAIDs:** nonsteroidal anti-inflammatory drugs; **PRM:** pulmonary recruitment manoeuvre; **RCT:** randomised controlled trial; **SD:** standard deviation; **STP:** shoulder-tip pain; **TLH:** total laparoscopic hysterectomy; **TSI:** trocar site infiltration; **VAS:** visual analogue scale

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Arden 2013	Did not assess STP
Asgari 2012	Intervention not of interest for this review
Asgari 2017	Did not assess STP
Beste 2006	Did not assess STP
Bogani 2014	Intervention not of interest for this review
Buck 2004	Did not assess STP
Butala 2013	Did not assess STP
Ceyhan 2005	Did not assess STP
Chaichian 2018	Not an RCT
Chakra 2001	Study only included women who were not having a general anaesthetic for their laparoscopy
Costello 2010	Did not assess STP
Dede 2015	Not an RCT
Demco 2001	Study only included women who were not having a general anaesthetic for their laparoscopy
El-Sherbiny 2009	Did not assess STP
Esin 2008	Letter to editor
Fagnoni 2003	Did not assess STP
Gisin 1998	Intervention not of interest for this review
Gordon 2002	Did not assess STP

Study	Reason for exclusion
Ikechebelu 2005	Intervention not of interest for this review
Ismail 2013	Intervention not of interest for this review
Jimenez 2014	Intervention not of interest for this review
Kayacan 2002	Did not assess STP
Kelly 1996	Did not assess STP
Khanna 2013	Wrong patient group (non-gynae)
Madsen 2016	Intervention not of interest for this review
Malhotra 2007	Not an RCT
Manjunath 2012	Did not assess STP
Nguyen 2002	Did not assess STP
Ott 1998	Did not assess STP
Paech 2008	Not an RCT
Parsanezhad 2003	Did not assess STP
Pellicano 1998	Did not assess STP
Rasooli 2015	Did not assess STP
Raymond 2010	Not an RCT
Readman 2004	Did not assess STP
Saleh 2001	Did not assess STP
Salmanli 1999	No methods or results available
Semm 1994	Not an RCT
Shaw 2001	Did not assess STP
Somaini 2014	Did not assess STP
Sripada 2006	Did not assess STP
Topcu 2014	Did not assess STP
Wang 2011	Did not assess STP

RCT: randomised controlled trial; **STP:** shoulder-tip pain

Characteristics of studies awaiting assessment *[ordered by study ID]*

Ryu 2017

Methods	<p>Study: RCT</p> <p>Country: Republic of Korea</p> <p>Type of surgery: elective gynaecological laparoscopy</p> <p>Number and type of laparoscopic ports: not described</p> <p>Distension medium and pressures: CO₂, pressure set at 14mm Hg throughout procedure</p> <p>Study duration: 8 months</p> <p>Informed consent: yes</p> <p>Funding sources: not described</p>
Participants	<p>A total of 90 women were randomised, 30 in each of the control and two intervention groups</p> <p>Reasons for exclusion/dropout: one woman dropped out after randomisation</p> <p>Age (mean \pm SD): Control 41.8 \pm 11.3; 40 cm H₂O group 38.7 \pm 9.3; 60 cm H₂O group 39.7 \pm 10.1</p> <p>BMI (kg/m², mean \pm SD) Control 23.0 \pm 3.7; 40 cm H₂O group 23.5 \pm 4.2; 60 cm H₂O group 22.9 \pm 4.1</p> <p>Ethnicity: not described</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • ASA 1-2 • undergoing any gynaecological laparoscopy <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Inability to understand the pain scale or to express their pain accurately, pregnancy, history of pulmonary or shoulder surgery, pulmonary disease such as pneumothorax or emphysema, chronic shoulder pain and conversion to laparotomy or incidental upper abdominal procedure owing to injury or adhesions.
Interventions	<p>Intervention:</p> <ol style="list-style-type: none"> 1. Saline instillation of 20ml/kg into the sub-diaphragmatic area at the end of the procedure with pulmonary recruitment manoeuvre (5 manual hyperinflation breathes for 5 seconds with an end-inspiratory plateau pressure of 40 cm/H₂O) 2. Saline instillation of 20ml/kg into the sub-diaphragmatic area at the end of the procedure with pulmonary recruitment manoeuvre (5 manual hyperinflation breathes for 5 seconds with an end-inspiratory plateau pressure of 60 cm/H₂O) <p>Control: standard technique for release of pneumoperitoneum</p>
Outcomes	<ul style="list-style-type: none"> • Post laparoscopic shoulder pain scores at 24 and 48 hours • Wound pain at 24 and 48 hours • Post-operative pulmonary complications
Notes	<p>Possible duplication of results in later study by same author</p>

Ryu 2018

Methods	<p>Study: RCT</p>
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Ryu 2018 (Continued)

	<p>Country: Republic of Korea</p> <p>Type of surgery: elective gynaecological laparoscopy</p> <p>Number and type of laparoscopic ports: not described</p> <p>Distension medium and pressures: CO₂, pressure set at 14mm Hg throughout procedure</p> <p>Study duration: not described</p> <p>Informed consent: yes</p> <p>Funding sources: not described</p>
Participants	<p>A total of 144 patients were randomised to either a control group (n=48) or one of two intervention groups (n=48 in each); SI (saline instillation) group or SI and RM (saline instillation and pulmonary recruitment manoeuvre) group</p> <p>Reasons for exclusion/dropout: none excluded after randomisation</p> <p>Age: (mean ± SD): Control 40±11; SI 39±13; SI + RM 40±10</p> <p>BMI: (kg/m², mean ± SD) Control 22.9±3.4; SI 22.9±3.0; SI +RM 23.5±4.9</p> <p>Ethnicity: not described</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • ASA 1-2 • undergoing any gynaecological laparoscopy <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Inability to understand the pain scale or to express their pain accurately, pregnancy, history of pulmonary or shoulder surgery, pulmonary disease such as pneumothorax or emphysema, chronic shoulder pain and conversion to laparotomy or incidental upper abdominal procedure owing to injury or adhesions
Interventions	<p>Intervention: Saline instillation (20 mL/kg warm isotonic saline instilled into subdiaphragmatic region) or Saline instillation (As above) with pulmonary recruitment manoeuvre (5 manual hyperinflation breathes for 5 seconds with an end-inspiratory plateau pressure of 40 cm/H₂O)</p> <p>Control: standard technique for release of pneumoperitoneum</p>
Outcomes	<ul style="list-style-type: none"> • Post laparoscopic shoulder pain scores at 24 and 48 hours.
Notes	

van Dijk 2018

Methods	<p>Study: RCT</p> <p>Country: Netherlands</p> <p>Type of surgery: Benign gynaecological laparoscopy</p> <p>Number and type of laparoscopic ports: Not described</p> <p>Distension medium and pressures: CO₂, pressure set at 14mm Hg throughout procedure</p> <p>Study duration: 23 months</p>
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van Dijk 2018 (Continued)

	Informed consent: Yes Funding sources: None
Participants	<p>A total of 200 women were randomised, 100 in the control group and 100 in the intervention group. Overall 23 women were excluded from final analysis leaving 88 women in the control group and 89 in the intervention group.</p> <p>Reasons for exclusion/dropout: Incorrect timing of questionnaire; 7 women did not return questionnaire, 15 women and one patient had a conversion to laparotomy</p> <p>Age (mean \pm SD): Control - 42 ± 9.2, intervention 43.2 ± 9.5</p> <p>BMI (kg/m², mean \pm SD): Control - 25.4 ± 4.0, intervention 26.2 ± 4.9</p> <p>Ethnicity:</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • ASA 1-2 • Elective gynaecological laparoscopies for benign conditions <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • None described
Interventions	<p>Intervention: 15-20 ml/kg warmed saline infused into abdomen at the end of the procedure with five pulmonary insufflation with a pressure of 40 cm H₂O</p> <p>Control: standard technique for release of pneumoperitoneum</p>
Outcomes	<ul style="list-style-type: none"> • Post-laparoscopic shoulder pain scores at 8, 24 and 48 hours. • Incidence of post-laparoscopic shoulder pain
Notes	

Characteristics of ongoing studies [ordered by study ID]

NCT03440086

Trial name or title	Temporary Application of Abdominal Jackson-Pratt Drain to Reduce Pain After Laparoscopic Surgery in Gynecology (DRAIN-1)
Methods	Randomized parallel group trial
Participants	94 participants (child, adult, older adult) undergoing laparoscopy
Interventions	Abdominal Jackson-Pratt drain for one hour at the end of laparoscopic procedure vs no drain
Outcomes	Pain at 6 and 24 hours after surgery, use of analgesic during the 48 hours after surgery
Starting date	1 June 2018
Contact information	Antonio Simone Laganà; antoniosimone.lagana@asst-settelaghi.it
Notes	

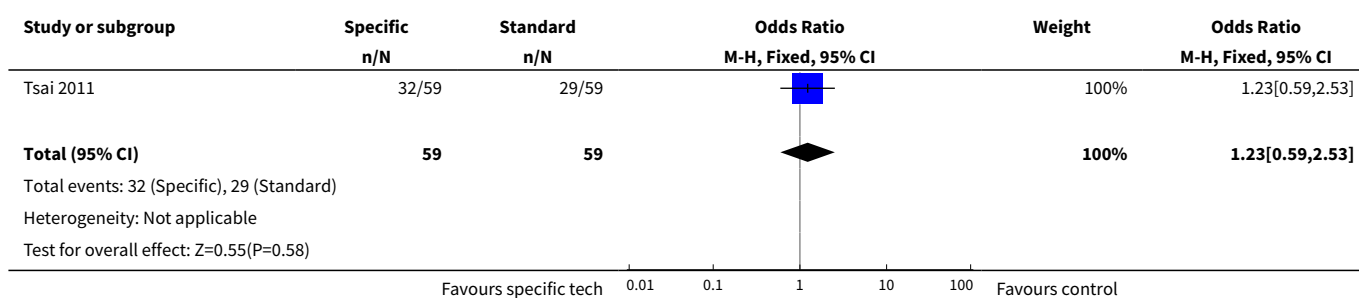
DATA AND ANALYSES

Comparison 1. Specific technique versus standard technique for releasing the pneumoperitoneum

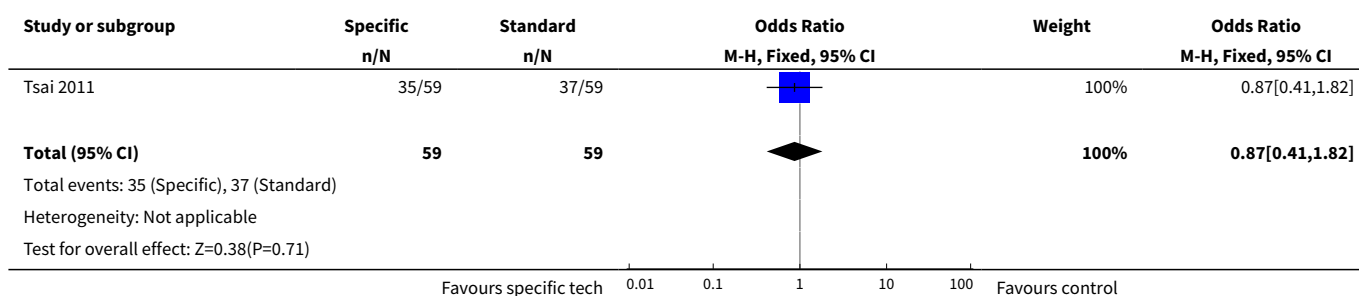
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of shoulder tip pain at 12 hours post-op	1	118	Odds Ratio (M-H, Fixed, 95% CI)	1.23 [0.59, 2.53]
2 Incidence of shoulder tip pain at 24 hours post-op	1	118	Odds Ratio (M-H, Fixed, 95% CI)	0.87 [0.41, 1.82]
3 Incidence of shoulder tip pain within 72 hours post op	6	731	Odds Ratio (M-H, Fixed, 95% CI)	0.77 [0.57, 1.05]
3.1 Postural change post-op vs control	1	131	Odds Ratio (M-H, Fixed, 95% CI)	0.71 [0.35, 1.46]
3.2 Pulmonary recruitment manoeuvre vs control	5	600	Odds Ratio (M-H, Fixed, 95% CI)	0.79 [0.56, 1.11]
4 Severity of postoperative shoulder tip pain at 3-6 hours post-op	3	466	Std. Mean Difference (IV, Fixed, 95% CI)	-0.29 [-0.48, -0.09]
5 Severity of postoperative shoulder tip pain at 12 hours post-op	4	381	Std. Mean Difference (IV, Fixed, 95% CI)	-0.58 [-0.78, -0.37]
5.1 Active intraperitoneal gas aspiration vs control	1	46	Std. Mean Difference (IV, Fixed, 95% CI)	-0.60 [-1.19, -0.01]
5.2 Pulmonary recruitment manoeuvre vs control	3	335	Std. Mean Difference (IV, Fixed, 95% CI)	-0.57 [-0.79, -0.35]
6 Severity of postoperative shoulder tip pain at 24 hours	5	670	Std. Mean Difference (IV, Fixed, 95% CI)	-0.66 [-0.82, -0.50]
6.1 EAV vs control	1	146	Std. Mean Difference (IV, Fixed, 95% CI)	-0.57 [-0.92, -0.22]
6.2 EAV & TSI vs control	1	143	Std. Mean Difference (IV, Fixed, 95% CI)	-0.66 [-1.02, -0.31]
6.3 PRM vs control	3	335	Std. Mean Difference (IV, Fixed, 95% CI)	-0.65 [-0.87, -0.43]
6.4 Active intraperitoneal gas aspiration vs control	1	46	Std. Mean Difference (IV, Fixed, 95% CI)	-1.06 [-1.69, -0.44]
7 Severity of shoulder tip pain at 36 hours post-op	1	100	Mean Difference (IV, Fixed, 95% CI)	-1.26 [-2.23, -0.29]
8 Severity of shoulder tip pain at 48 hours post op	3	524	Mean Difference (IV, Fixed, 95% CI)	-0.72 [-0.99, -0.45]
8.1 EAV vs control	1	146	Mean Difference (IV, Fixed, 95% CI)	-0.58 [-1.10, -0.06]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.2 EAV & TSI vs control	1	143	Mean Difference (IV, Fixed, 95% CI)	-0.50 [-1.02, 0.02]
8.3 PRM vs control	2	235	Mean Difference (IV, Fixed, 95% CI)	-0.92 [-1.31, -0.52]
9 Adverse events	1	74	Odds Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Analgesia usage	4	570	Std. Mean Difference (IV, Fixed, 95% CI)	-0.53 [-0.70, -0.35]

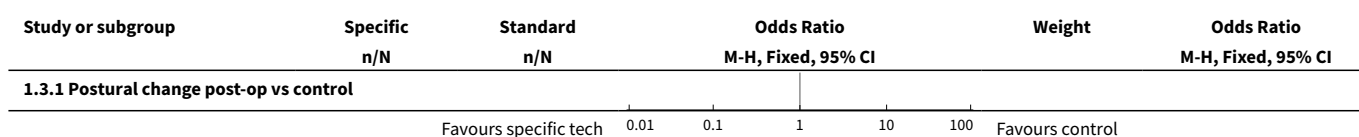
Analysis 1.1. Comparison 1 Specific technique versus standard technique for releasing the pneumoperitoneum, Outcome 1 Incidence of shoulder tip pain at 12 hours post-op.

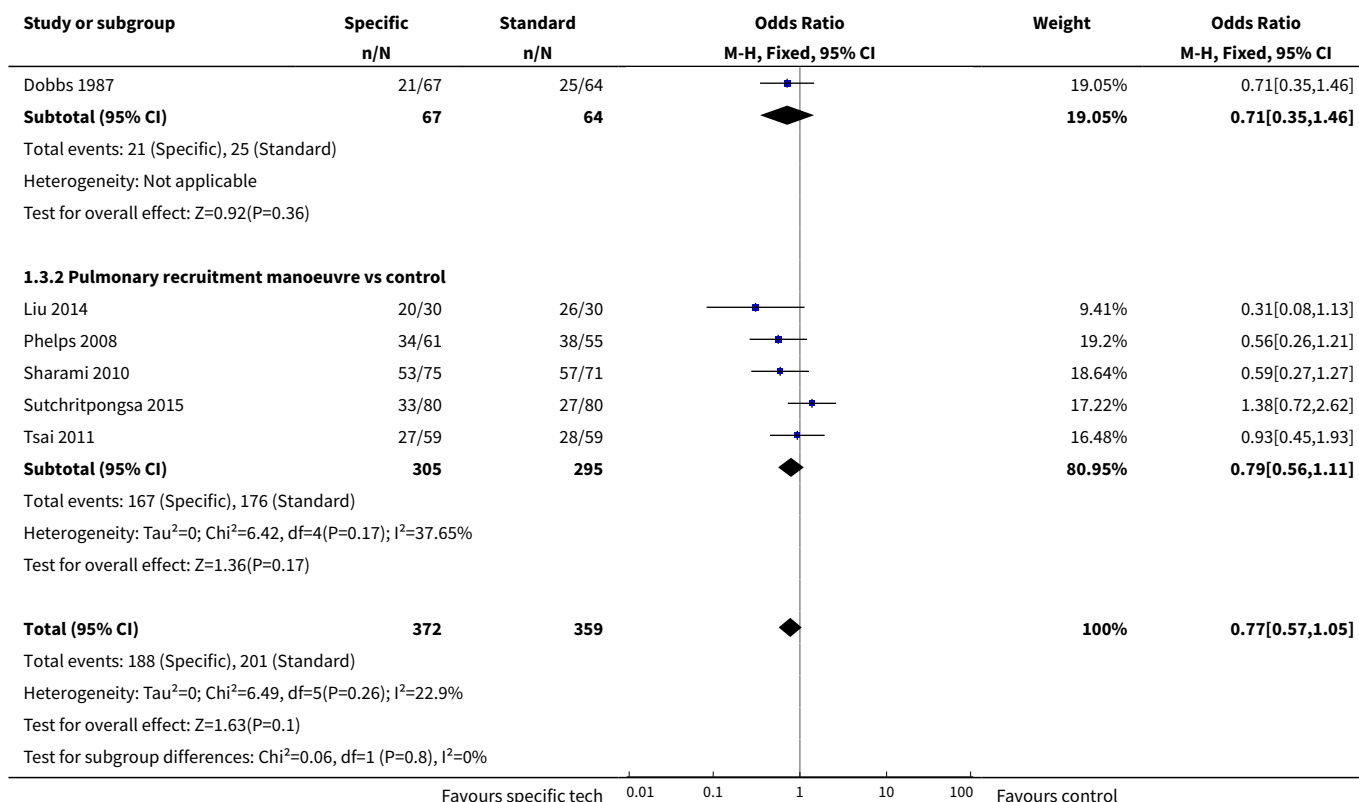


Analysis 1.2. Comparison 1 Specific technique versus standard technique for releasing the pneumoperitoneum, Outcome 2 Incidence of shoulder tip pain at 24 hours post-op.

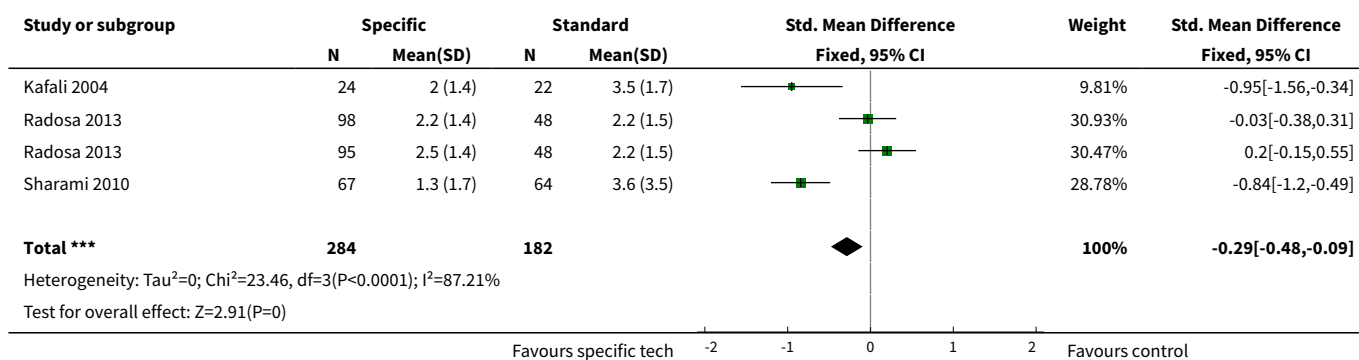


Analysis 1.3. Comparison 1 Specific technique versus standard technique for releasing the pneumoperitoneum, Outcome 3 Incidence of shoulder tip pain within 72 hours post op.

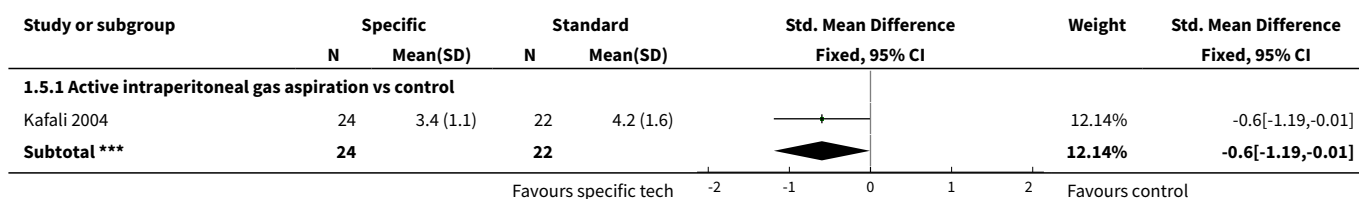


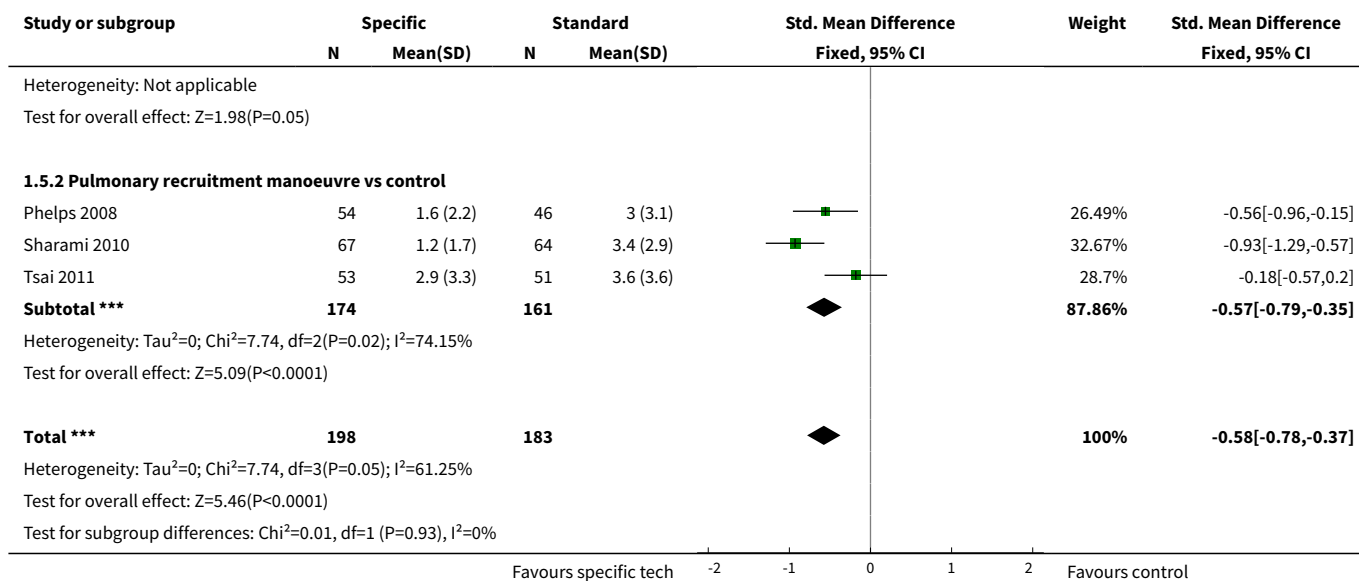


Analysis 1.4. Comparison 1 Specific technique versus standard technique for releasing the pneumoperitoneum, Outcome 4 Severity of postoperative shoulder tip pain at 3-6 hours post-op.

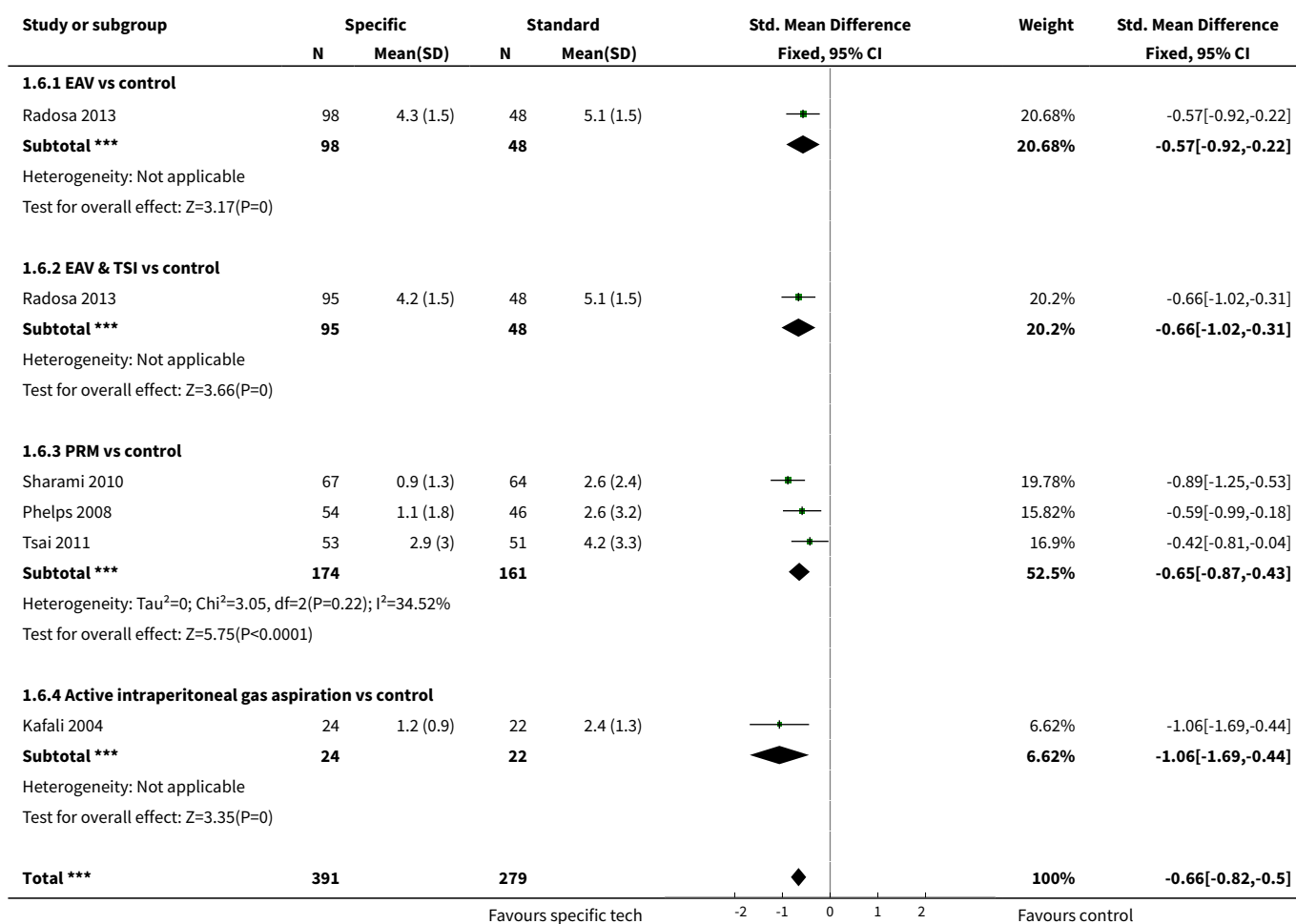


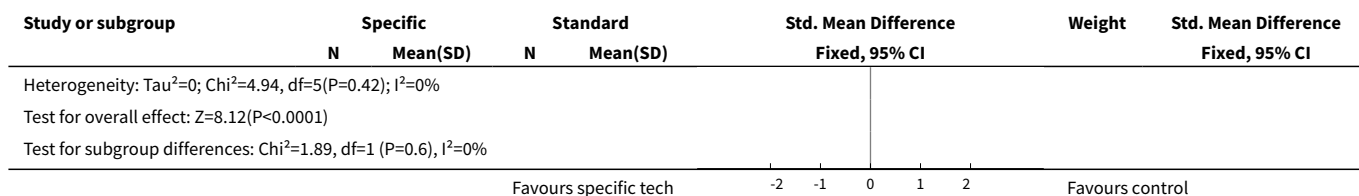
Analysis 1.5. Comparison 1 Specific technique versus standard technique for releasing the pneumoperitoneum, Outcome 5 Severity of postoperative shoulder tip pain at 12 hours post-op.



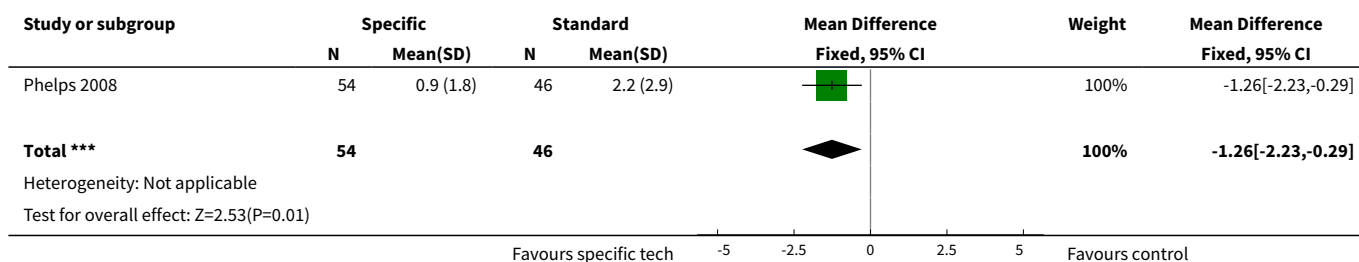


Analysis 1.6. Comparison 1 Specific technique versus standard technique for releasing the pneumoperitoneum, Outcome 6 Severity of postoperative shoulder tip pain at 24 hours.

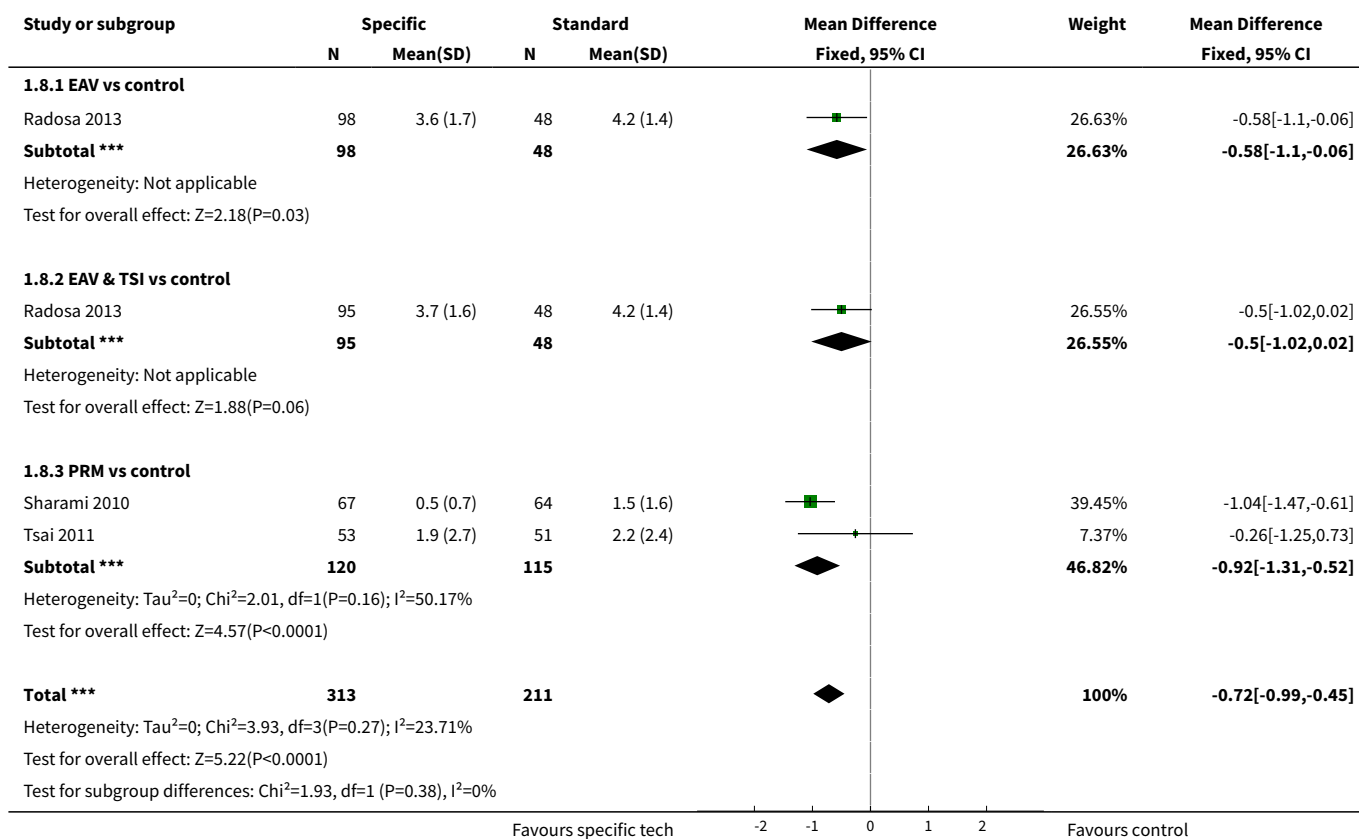





Analysis 1.7. Comparison 1 Specific technique versus standard technique for releasing the pneumoperitoneum, Outcome 7 Severity of shoulder tip pain at 36 hours post-op.










Analysis 1.8. Comparison 1 Specific technique versus standard technique for releasing the pneumoperitoneum, Outcome 8 Severity of shoulder tip pain at 48 hours post op.



Analysis 1.9. Comparison 1 Specific technique versus standard technique for releasing the pneumoperitoneum, Outcome 9 Adverse events.

Study or subgroup	Specific n/N	Standard n/N	Odds Ratio M-H, Fixed, 95% CI	Weight	Odds Ratio M-H, Fixed, 95% CI
Leelasuwattanakul 2016	0/37	0/37			Not estimable
Total (95% CI)	37	37			Not estimable
Total events: 0 (Specific), 0 (Standard)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
					

Analysis 1.10. Comparison 1 Specific technique versus standard technique for releasing the pneumoperitoneum, Outcome 10 Analgesia usage.

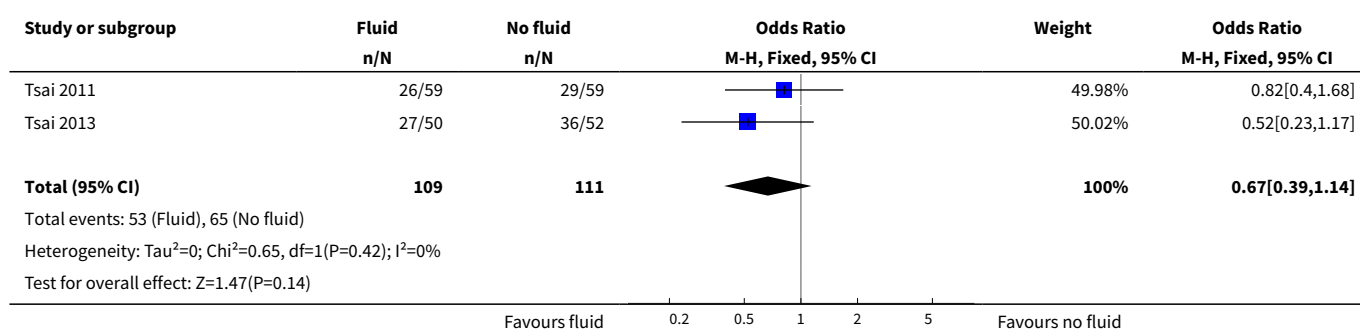
Study or subgroup	Specific		Standard		Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)			
Kafali 2004	24	12.7 (1.6)	22	22.3 (2.9)		2.84%	-4.08[-5.12,-3.03]
Radosa 2013	98	2.9 (1.2)	48	3.7 (2.3)		25.33%	-0.5[-0.85,-0.15]
Sharami 2010	67	95.5 (27)	64	112.5 (45.1)		25.78%	-0.46[-0.8,-0.11]
Radosa 2013	95	2.9 (1.4)	48	3.7 (2.3)		25.2%	-0.45[-0.8,-0.1]
Tsai 2011	53	52.3 (37.2)	51	62.8 (46.1)		20.85%	-0.25[-0.64,0.14]
Total ***	337		233			100%	-0.53[-0.7,-0.35]
Heterogeneity: Tau ² =0; Chi ² =46.62, df=4(P<0.0001); I ² =91.42%							
Test for overall effect: Z=5.85(P<0.0001)							
							

Comparison 2. Fluid instillation versus no fluid instillation

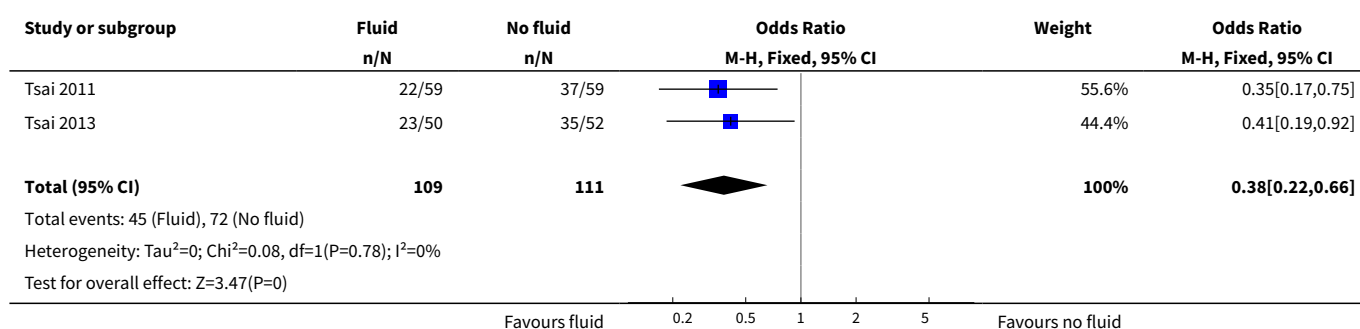
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of shoulder tip pain at 12 hours post-op	2	220	Odds Ratio (M-H, Fixed, 95% CI)	0.67 [0.39, 1.14]
2 Incidence of shoulder tip pain at 24 hours post-op	2	220	Odds Ratio (M-H, Fixed, 95% CI)	0.38 [0.22, 0.66]
3 Incidence of shoulder tip pain at 48 hours post-op	2	220	Odds Ratio (M-H, Fixed, 95% CI)	0.38 [0.21, 0.67]
4 Severity of shoulder tip pain at 12 hours post-op	2	205	Mean Difference (IV, Fixed, 95% CI)	-1.69 [-2.55, -0.83]
5 Severity of shoulder tip pain at 24 hours post-op	2	205	Mean Difference (IV, Fixed, 95% CI)	-2.27 [-3.06, -1.48]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6 Severity of shoulder tip pain at 48 hours post-op	2	205	Mean Difference (IV, Fixed, 95% CI)	-1.44 [-2.07, -0.81]
7 Analgesia usage (meperidine mg)	2	205	Mean Difference (IV, Fixed, 95% CI)	-12.02 [-23.97, -0.06]

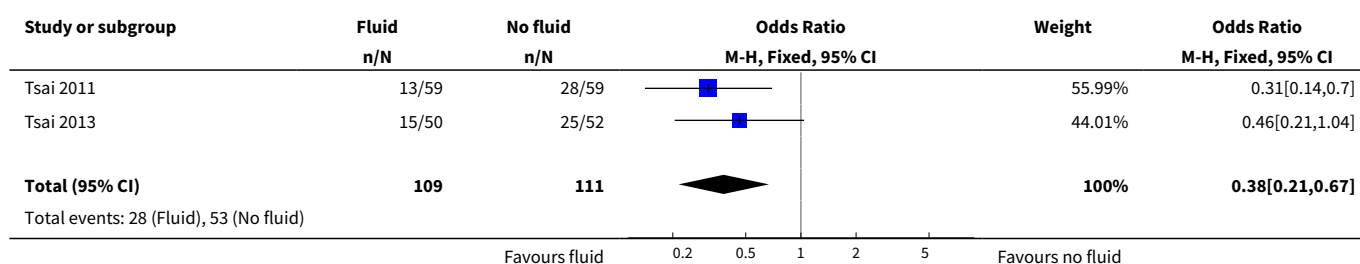
Analysis 2.1. Comparison 2 Fluid instillation versus no fluid instillation, Outcome 1 Incidence of shoulder tip pain at 12 hours post-op.

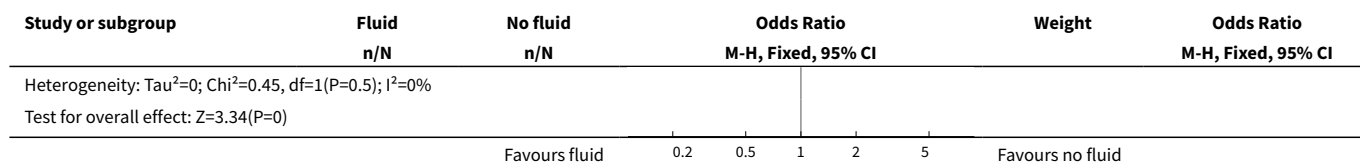


Analysis 2.2. Comparison 2 Fluid instillation versus no fluid instillation, Outcome 2 Incidence of shoulder tip pain at 24 hours post-op.

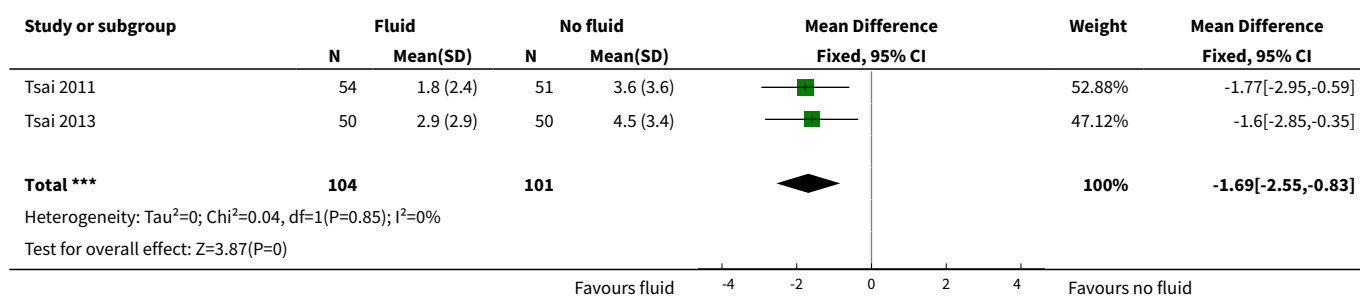


Analysis 2.3. Comparison 2 Fluid instillation versus no fluid instillation, Outcome 3 Incidence of shoulder tip pain at 48 hours post-op.

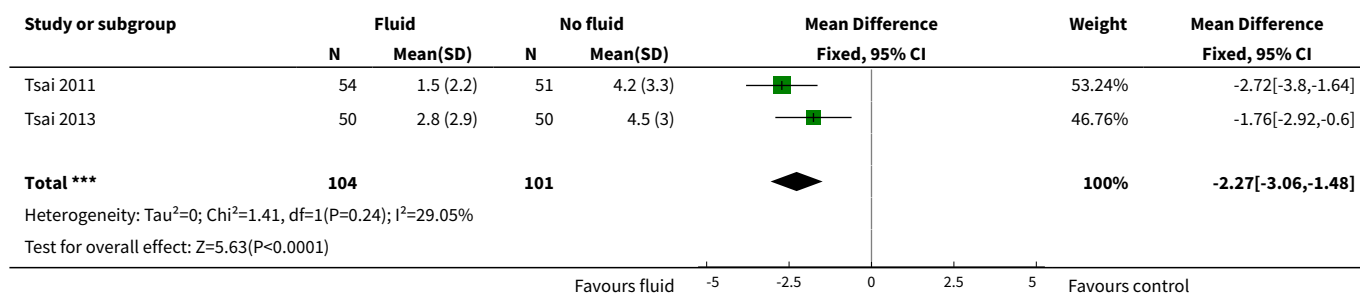




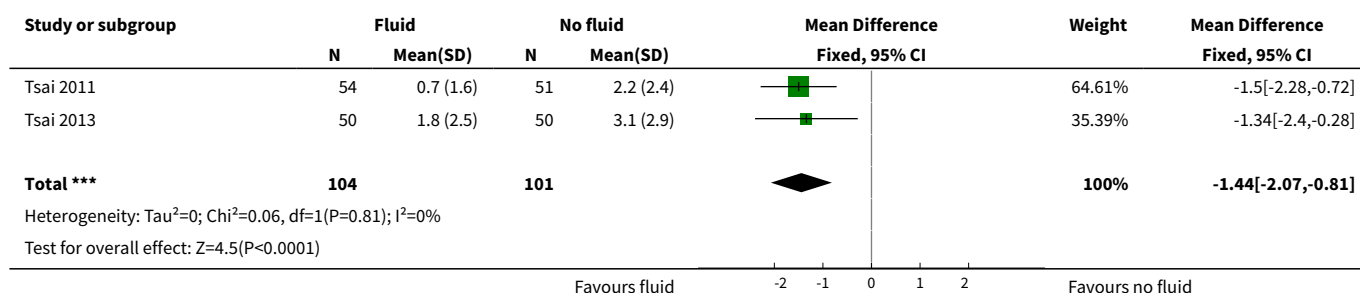
Analysis 2.4. Comparison 2 Fluid instillation versus no fluid instillation, Outcome 4 Severity of shoulder tip pain at 12 hours post-op.



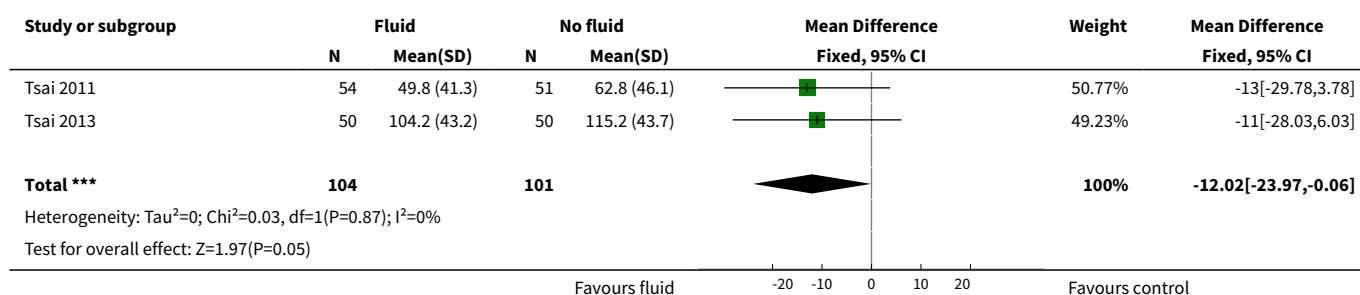
Analysis 2.5. Comparison 2 Fluid instillation versus no fluid instillation, Outcome 5 Severity of shoulder tip pain at 24 hours post-op.



Analysis 2.6. Comparison 2 Fluid instillation versus no fluid instillation, Outcome 6 Severity of shoulder tip pain at 48 hours post-op.



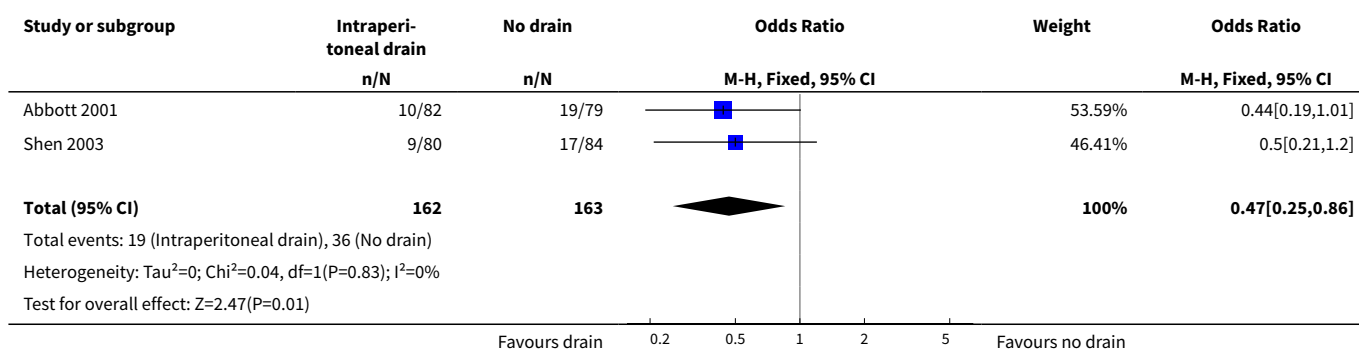
Analysis 2.7. Comparison 2 Fluid instillation versus no fluid instillation, Outcome 7 Analgesia usage (meperidine mg).



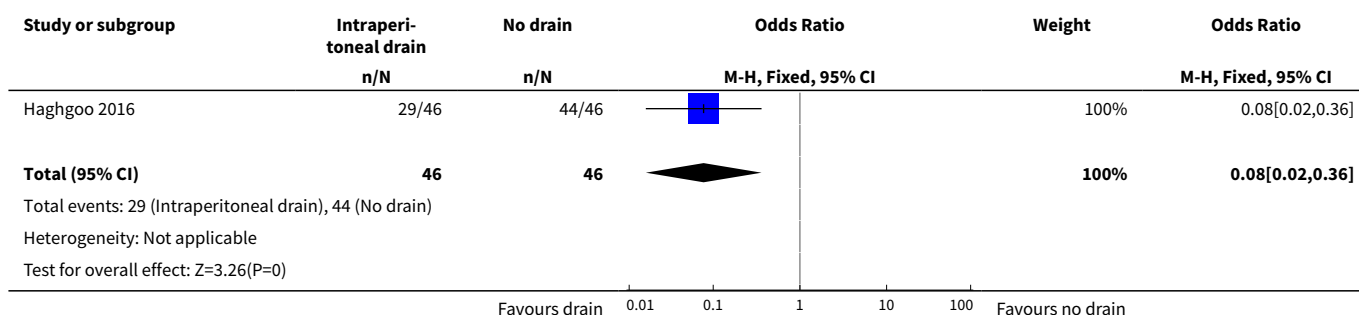
Comparison 3. Intraperitoneal drain versus no intraperitoneal drain

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of shoulder tip pain at 3-4 hours post-op	2	325	Odds Ratio (M-H, Fixed, 95% CI)	0.47 [0.25, 0.86]
2 Incidence of shoulder tip pain at 12 hours post-op	1	92	Odds Ratio (M-H, Fixed, 95% CI)	0.08 [0.02, 0.36]
3 Incidence of shoulder tip pain at 24 hours post-op	3	417	Odds Ratio (M-H, Fixed, 95% CI)	0.30 [0.20, 0.46]
4 Incidence of shoulder tip pain at 48 hours post-op	3	417	Odds Ratio (M-H, Fixed, 95% CI)	0.40 [0.21, 0.74]
5 Severity of shoulder tip pain at 3-4 hours	2	231	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.29, 0.10]
6 Severity of shoulder tip pain at 12 hours	2	156	Mean Difference (IV, Fixed, 95% CI)	-1.69 [-2.20, -1.19]
7 Severity of shoulder tip pain at 24 hours	3	320	Mean Difference (IV, Fixed, 95% CI)	-1.85 [-2.15, -1.55]
8 Severity of shoulder tip pain at 48 hours	3	320	Mean Difference (IV, Fixed, 95% CI)	-0.70 [-0.95, -0.44]
9 Severity of shoulder tip pain at 72 hours	1	67	Mean Difference (IV, Fixed, 95% CI)	-0.8 [-1.55, -0.05]
10 Severity of shoulder tip pain at 96 hours	1	67	Mean Difference (IV, Fixed, 95% CI)	-0.54 [-1.20, 0.12]
11 Severity of shoulder tip pain at 120 hours	1	67	Mean Difference (IV, Fixed, 95% CI)	-0.13 [-0.55, 0.29]
12 Analgesia usage	2	253	Std. Mean Difference (IV, Fixed, 95% CI)	-1.84 [-2.14, -1.54]

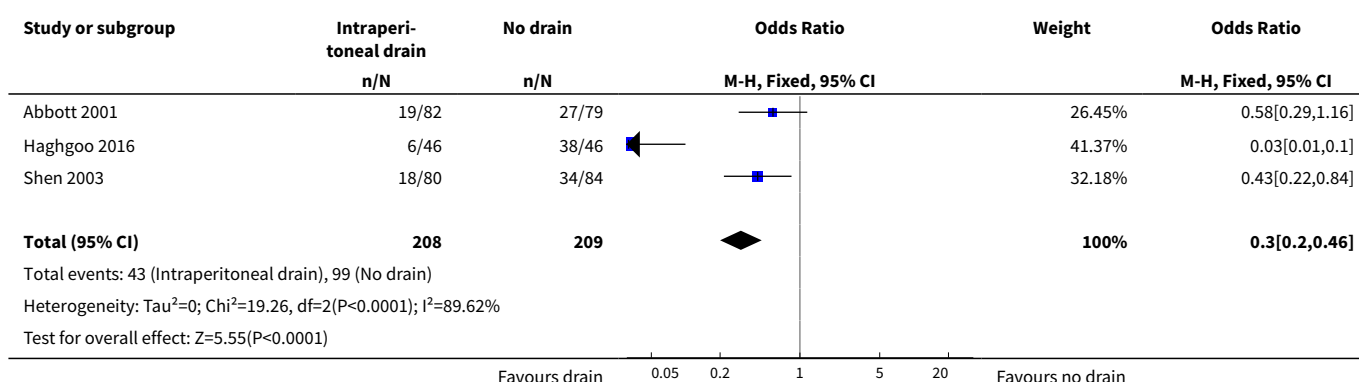
Analysis 3.1. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 1 Incidence of shoulder tip pain at 3-4 hours post-op.



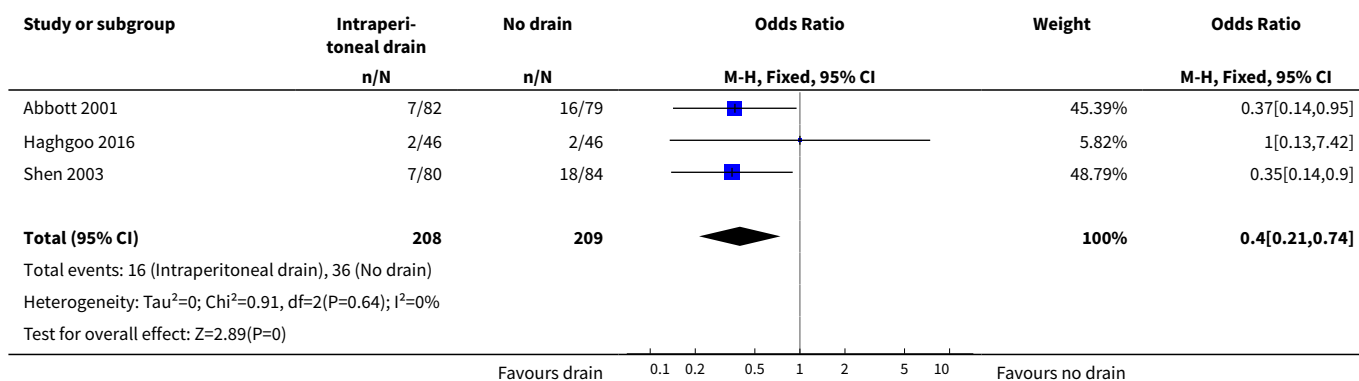
Analysis 3.2. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 2 Incidence of shoulder tip pain at 12 hours post-op.



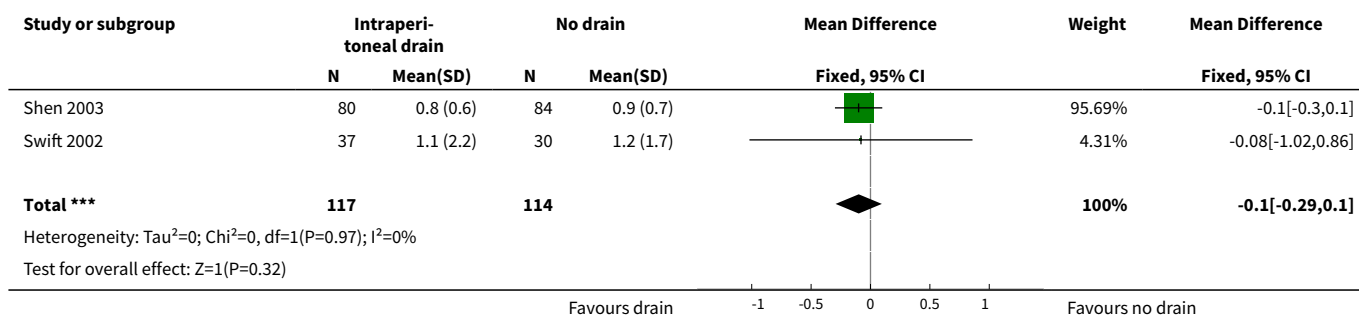
Analysis 3.3. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 3 Incidence of shoulder tip pain at 24 hours post-op.



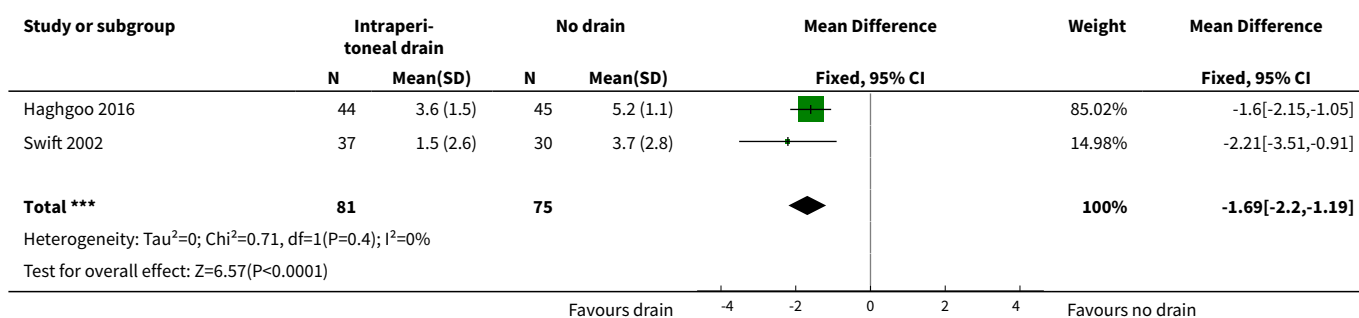
Analysis 3.4. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 4 Incidence of shoulder tip pain at 48 hours post-op.



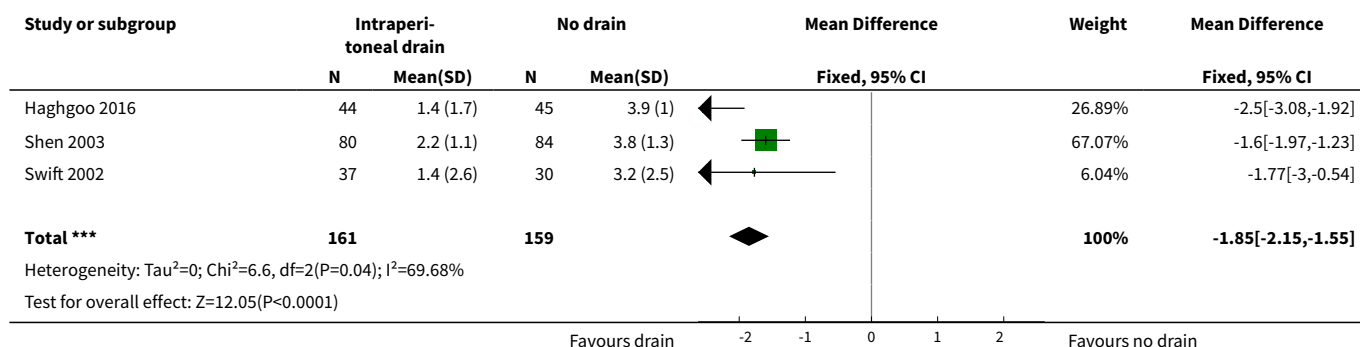
Analysis 3.5. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 5 Severity of shoulder tip pain at 3-4 hours.



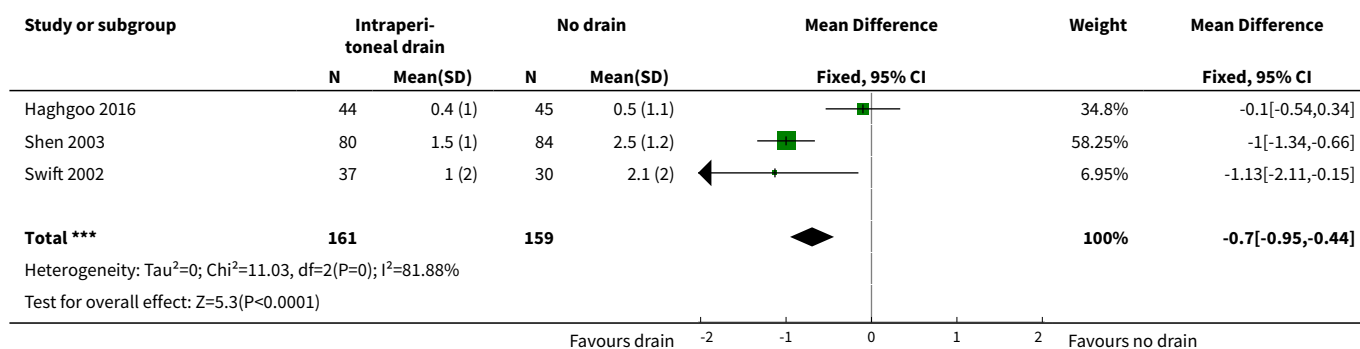
Analysis 3.6. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 6 Severity of shoulder tip pain at 12 hours.



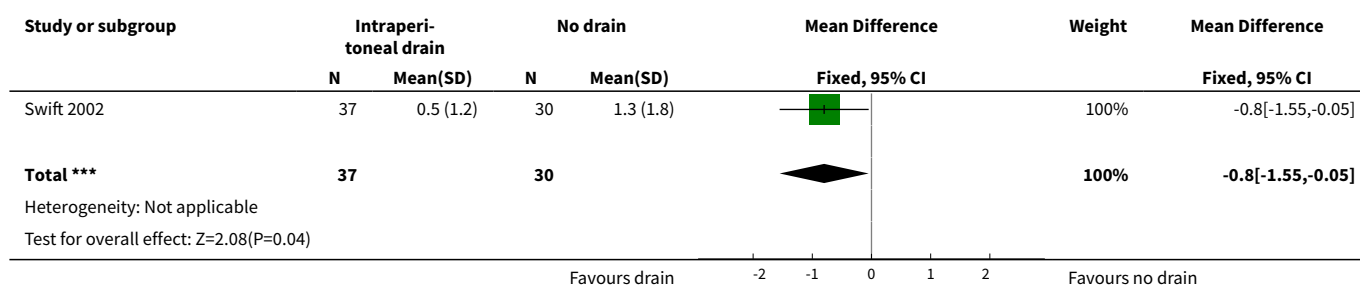
Analysis 3.7. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 7 Severity of shoulder tip pain at 24 hours.



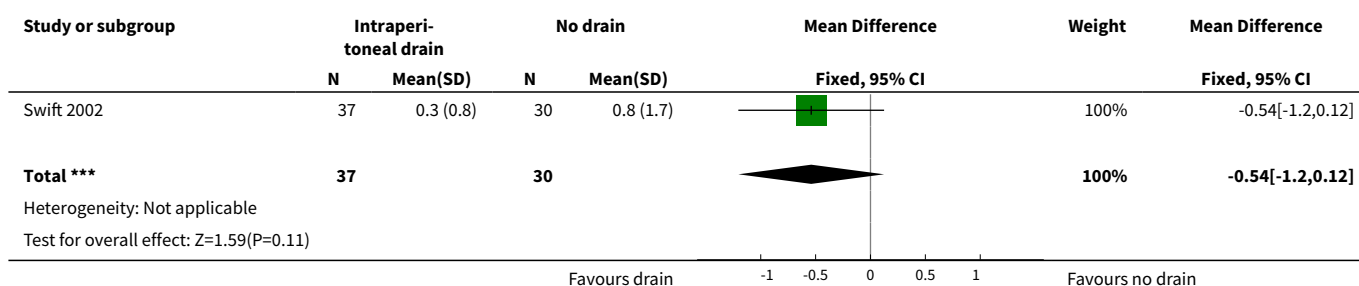
Analysis 3.8. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 8 Severity of shoulder tip pain at 48 hours.



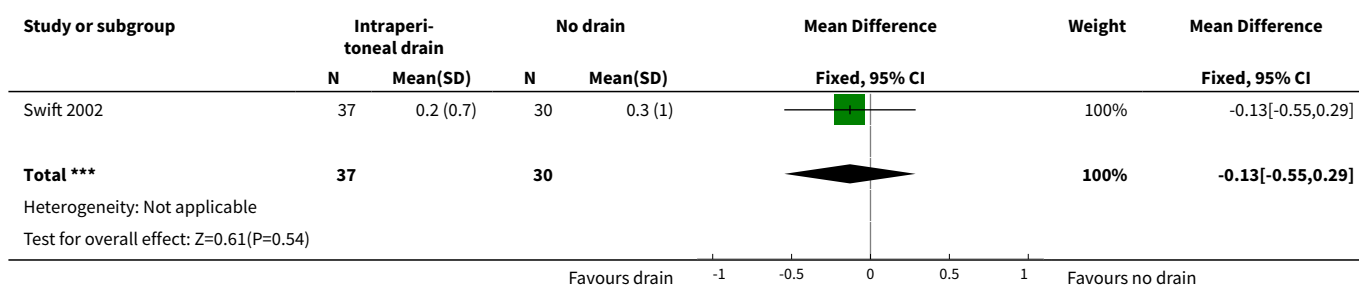
Analysis 3.9. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 9 Severity of shoulder tip pain at 72 hours.



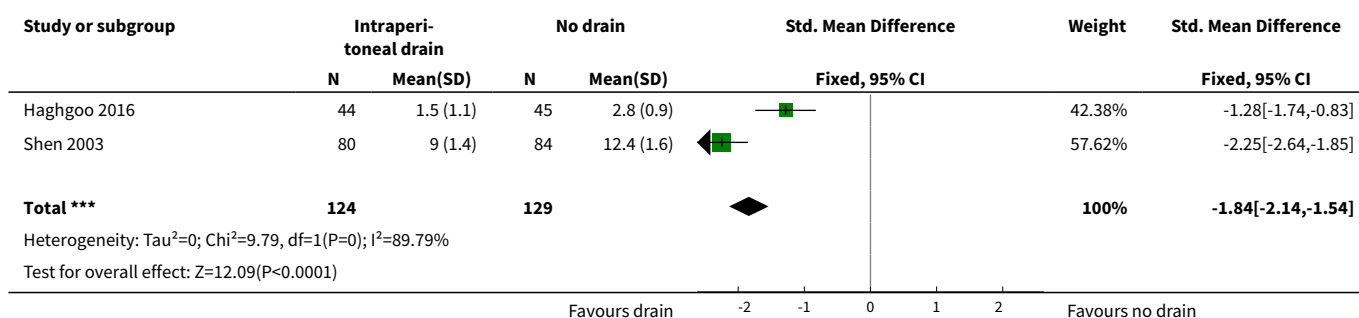
Analysis 3.10. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 10 Severity of shoulder tip pain at 96 hours.



Analysis 3.11. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 11 Severity of shoulder tip pain at 120 hours.



Analysis 3.12. Comparison 3 Intraperitoneal drain versus no intraperitoneal drain, Outcome 12 Analgesia usage.

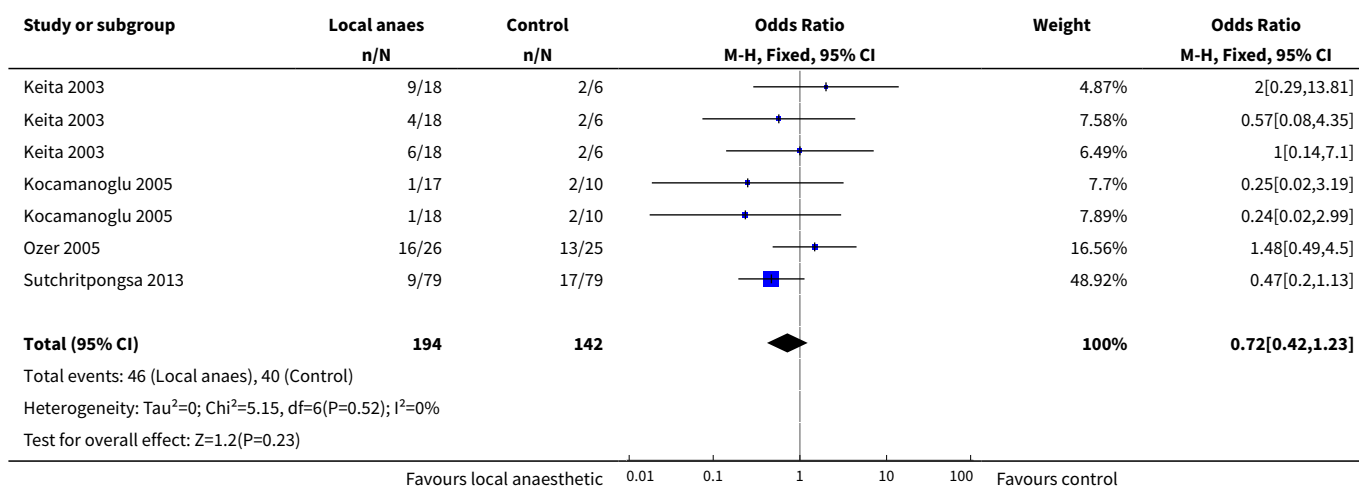


Comparison 4. Subdiaphragmatic intraperitoneal local anaesthetic versus control

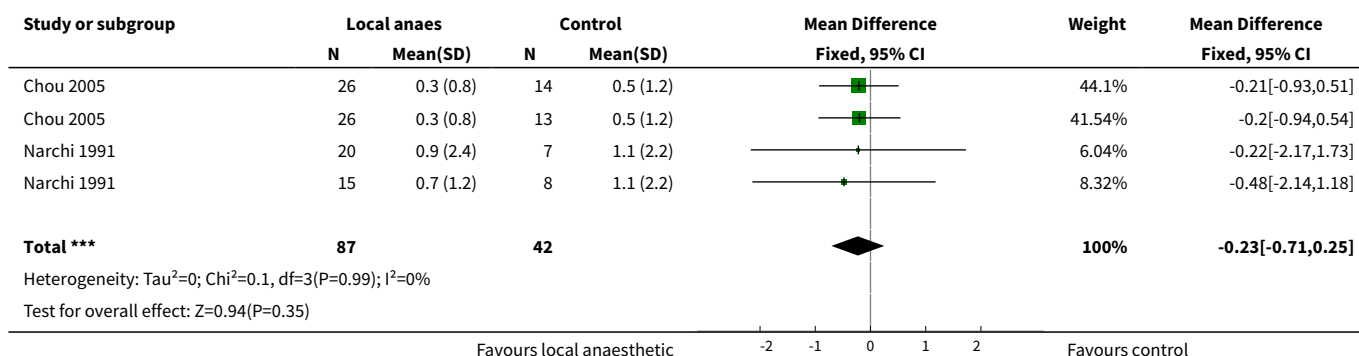
Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Incidence of shoulder tip pain	4	336	Odds Ratio (M-H, Fixed, 95% CI)	0.72 [0.42, 1.23]
2 Severity of postoperative shoulder tip pain at 2 hours	2	129	Mean Difference (IV, Fixed, 95% CI)	-0.23 [-0.71, 0.25]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Severity of postoperative shoulder tip pain at 4 hours	1	79	Mean Difference (IV, Fixed, 95% CI)	-1.05 [-2.17, 0.06]
4 Severity of postoperative shoulder tip pain at 8 hours	2	129	Mean Difference (IV, Fixed, 95% CI)	-0.95 [-1.70, -0.19]
5 Severity of postoperative shoulder tip pain at 12-16 hours	1	79	Mean Difference (IV, Fixed, 95% CI)	-1.08 [-2.18, 0.03]
6 Severity of postoperative shoulder tip pain at 24 hours	1	50	Mean Difference (IV, Fixed, 95% CI)	-1.13 [-2.52, 0.26]
7 Severity of postoperative shoulder tip pain at 36 hours	1	50	Mean Difference (IV, Fixed, 95% CI)	-1.64 [-3.36, 0.09]
8 Severity of postoperative shoulder tip pain at 48 hours	1	50	Mean Difference (IV, Fixed, 95% CI)	-1.00 [-2.06, 0.06]
9 Adverse events	3	165	Odds Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Analgesia usage	2	129	Std. Mean Difference (IV, Fixed, 95% CI)	-0.57 [-0.94, -0.21]

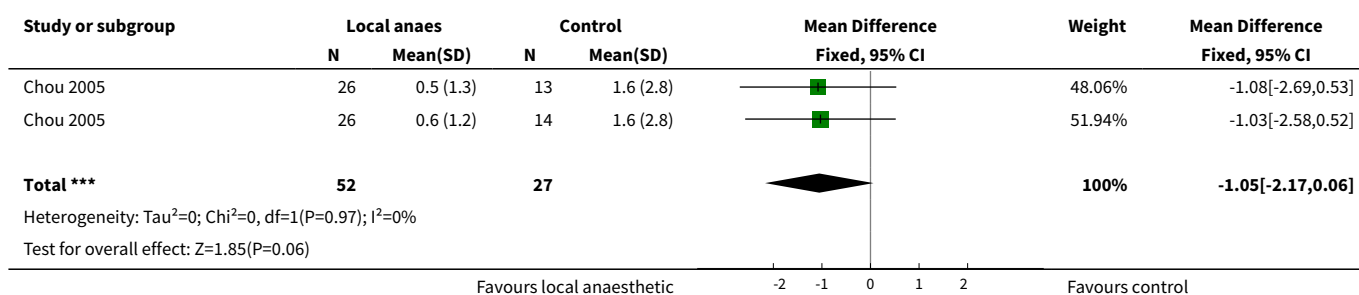
Analysis 4.1. Comparison 4 Subdiaphragmatic intraperitoneal local anaesthetic versus control, Outcome 1 Incidence of shoulder tip pain.



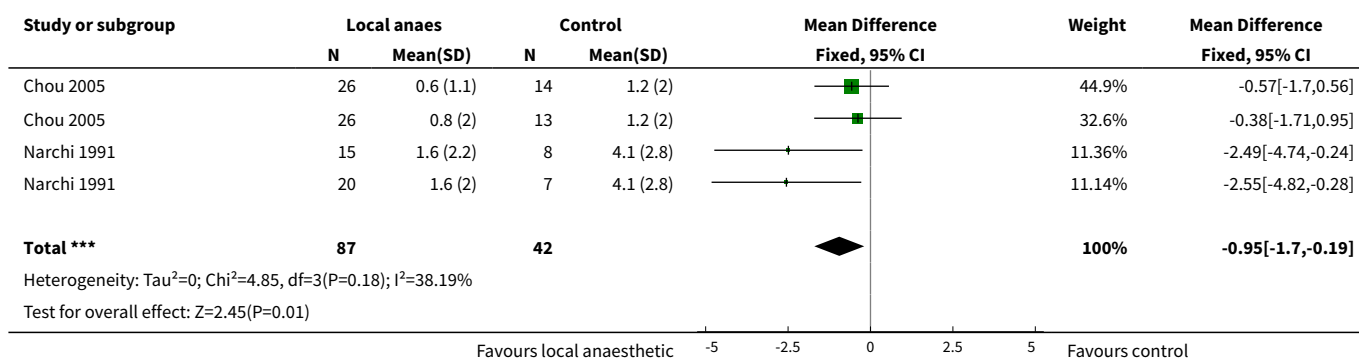
Analysis 4.2. Comparison 4 Subdiaphragmatic intraperitoneal local anaesthetic versus control, Outcome 2 Severity of postoperative shoulder tip pain at 2 hours.



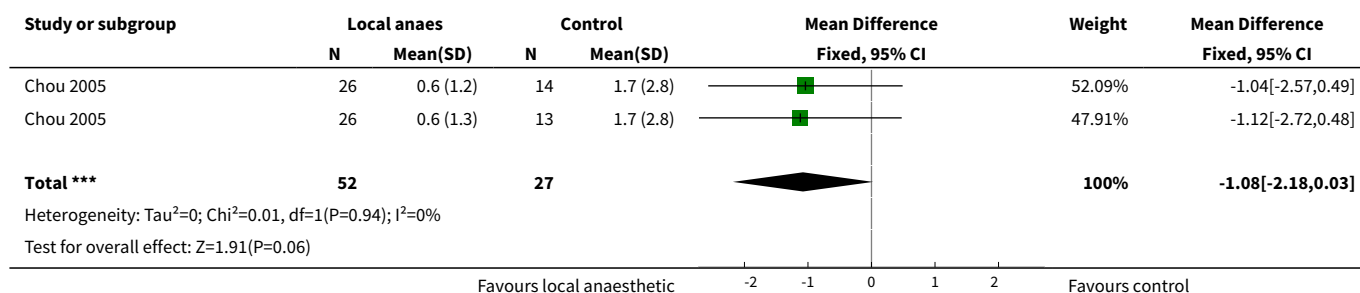
Analysis 4.3. Comparison 4 Subdiaphragmatic intraperitoneal local anaesthetic versus control, Outcome 3 Severity of postoperative shoulder tip pain at 4 hours.



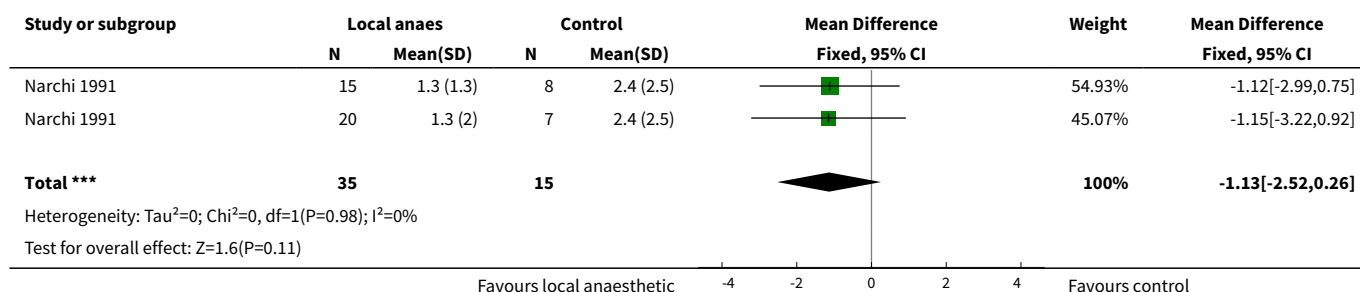
Analysis 4.4. Comparison 4 Subdiaphragmatic intraperitoneal local anaesthetic versus control, Outcome 4 Severity of postoperative shoulder tip pain at 8 hours.



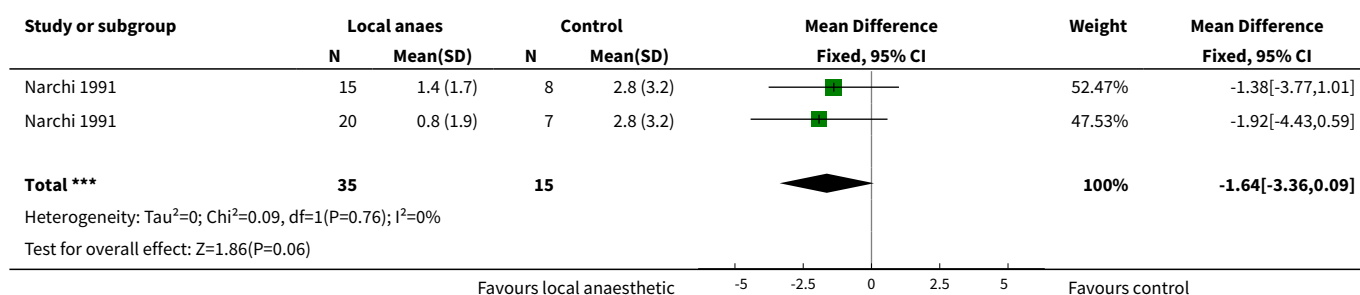
Analysis 4.5. Comparison 4 Subdiaphragmatic intraperitoneal local anaesthetic versus control, Outcome 5 Severity of postoperative shoulder tip pain at 12-16 hours.



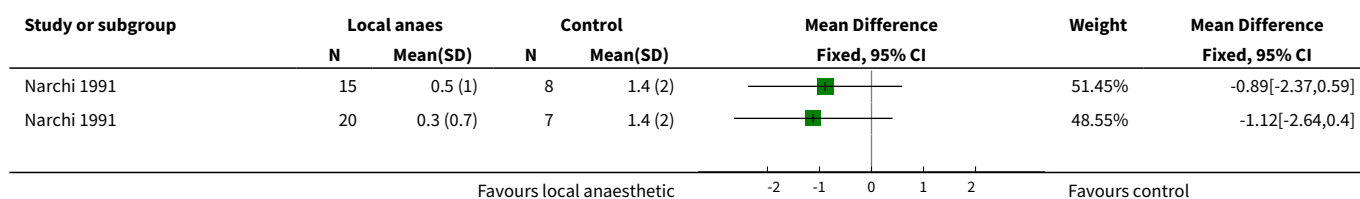
Analysis 4.6. Comparison 4 Subdiaphragmatic intraperitoneal local anaesthetic versus control, Outcome 6 Severity of postoperative shoulder tip pain at 24 hours.

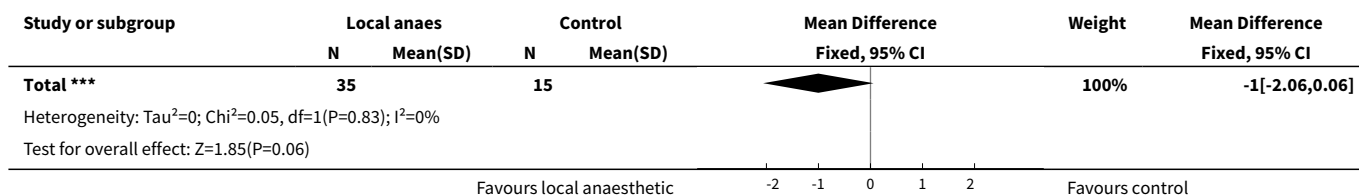


Analysis 4.7. Comparison 4 Subdiaphragmatic intraperitoneal local anaesthetic versus control, Outcome 7 Severity of postoperative shoulder tip pain at 36 hours.

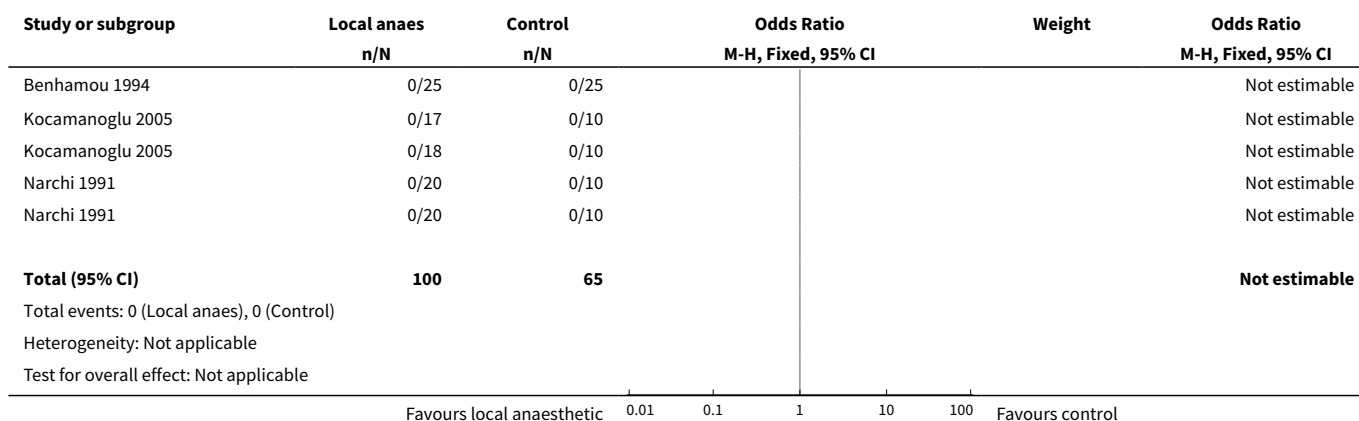


Analysis 4.8. Comparison 4 Subdiaphragmatic intraperitoneal local anaesthetic versus control, Outcome 8 Severity of postoperative shoulder tip pain at 48 hours.

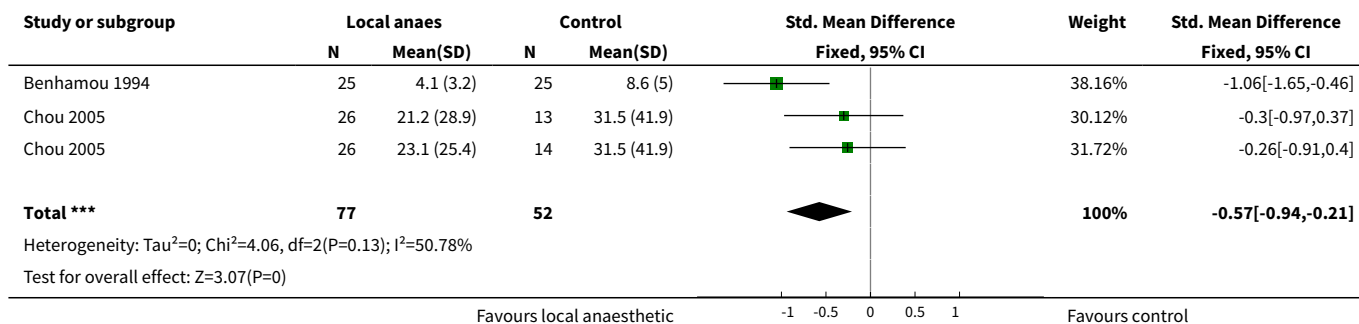




Analysis 4.9. Comparison 4 Subdiaphragmatic intraperitoneal local anaesthetic versus control, Outcome 9 Adverse events.



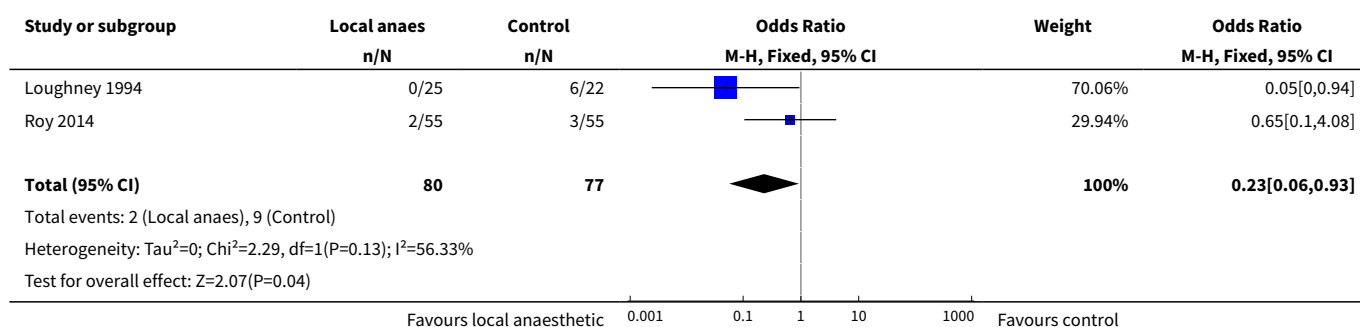
Analysis 4.10. Comparison 4 Subdiaphragmatic intraperitoneal local anaesthetic versus control, Outcome 10 Analgesia usage.



Comparison 5. Local anaesthetic to peritoneal cavity (not subdiaphragmatic) versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of shoulder tip pain within 24 hours post-op	2	157	Odds Ratio (M-H, Fixed, 95% CI)	0.23 [0.06, 0.93]

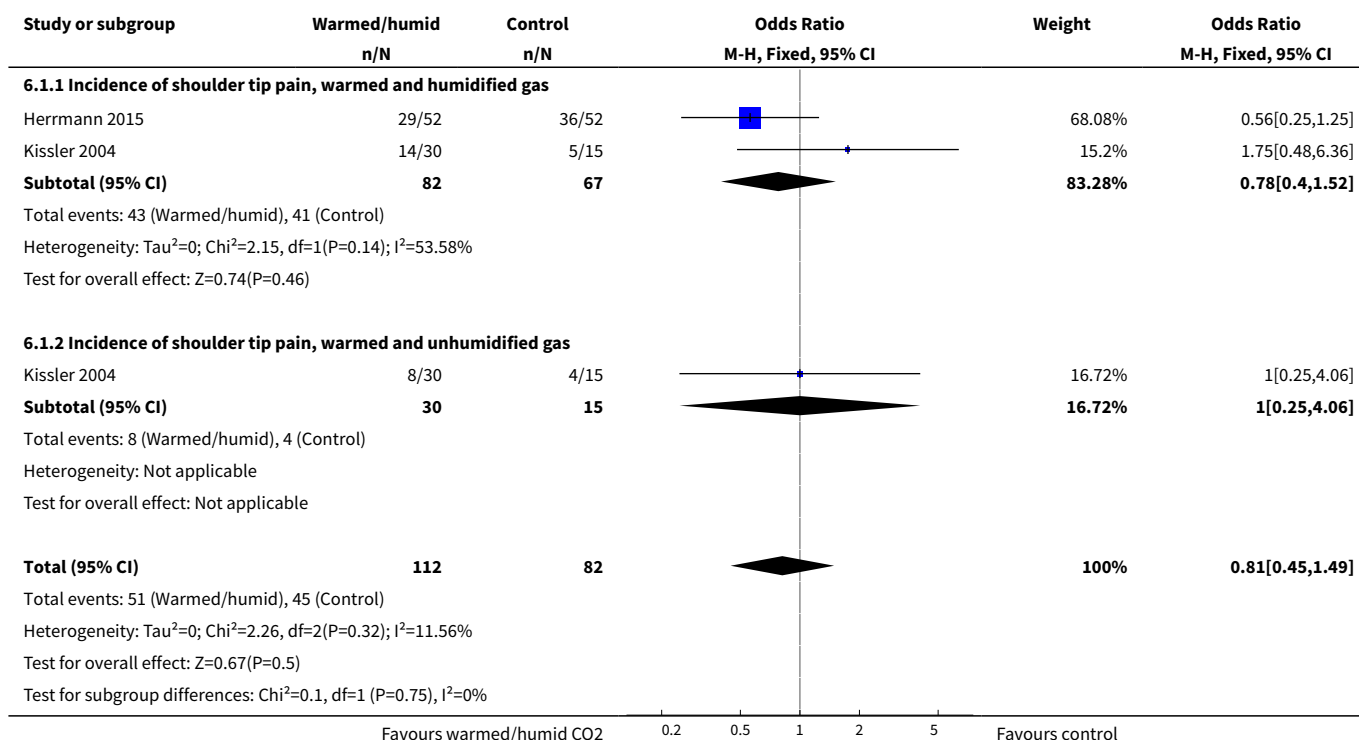
Analysis 5.1. Comparison 5 Local anaesthetic to peritoneal cavity (not subdiaphragmatic) versus control, Outcome 1 Incidence of shoulder tip pain within 24 hours post-op.



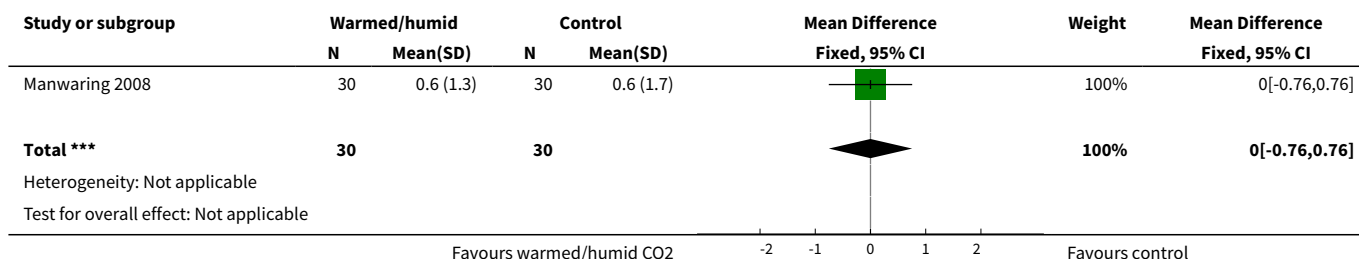
Comparison 6. Warmed +/- humidified CO₂ versus unwarmed and unhumidified CO₂

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of shoulder tip pain	2	194	Odds Ratio (M-H, Fixed, 95% CI)	0.81 [0.45, 1.49]
1.1 Incidence of shoulder tip pain, warmed and humidified gas	2	149	Odds Ratio (M-H, Fixed, 95% CI)	0.78 [0.40, 1.52]
1.2 Incidence of shoulder tip pain, warmed and unhumidified gas	1	45	Odds Ratio (M-H, Fixed, 95% CI)	1.0 [0.25, 4.06]
2 Severity of shoulder tip pain at 1 hour post-op	1	60	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.76, 0.76]
3 Severity of shoulder tip pain at 2 hours post-op	2	155	Mean Difference (IV, Fixed, 95% CI)	-0.19 [-0.61, 0.23]
4 Severity of shoulder tip pain at 4 hours post-op	2	157	Mean Difference (IV, Fixed, 95% CI)	0.05 [-0.26, 0.36]
5 Severity of shoulder tip pain at 24 hours post-op	2	157	Mean Difference (IV, Fixed, 95% CI)	0.11 [-0.75, 0.97]
6 Severity of shoulder tip pain at 48 hours post-op	1	96	Mean Difference (IV, Fixed, 95% CI)	-0.39 [-1.36, 0.58]
7 Analgesia usage (morphine mg)	1	95	Mean Difference (IV, Fixed, 95% CI)	-4.97 [-11.25, 1.31]

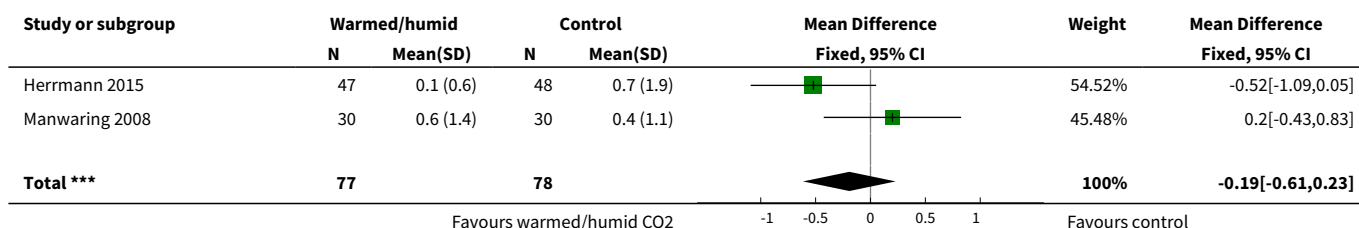
Analysis 6.1. Comparison 6 Warmed +/- humidified CO₂ versus unwarmed and unhumidified CO₂, Outcome 1 Incidence of shoulder tip pain.



Analysis 6.2. Comparison 6 Warmed +/- humidified CO₂ versus unwarmed and unhumidified CO₂, Outcome 2 Severity of shoulder tip pain at 1 hour post-op.






Analysis 6.3. Comparison 6 Warmed +/- humidified CO₂ versus unwarmed and unhumidified CO₂, Outcome 3 Severity of shoulder tip pain at 2 hours post-op.






Study or subgroup	Warmed/humid		Control		Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)			
Heterogeneity: Tau²=0; Chi²=2.77, df=1(P=0.1); I²=63.91%							
Test for overall effect: Z=0.89(P=0.37)							
Favours warmed/humid CO2					-1 -0.5 0 0.5 1	Favours control	

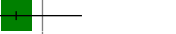

Analysis 6.4. Comparison 6 Warmed +/- humidified CO₂ versus unwarmed and unhumidified CO₂, Outcome 4 Severity of shoulder tip pain at 4 hours post-op.

Study or subgroup	Warmed/humid		Control		Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)			
Herrmann 2015	49	0.2 (0.7)	48	0.2 (0.9)		90.48%	0.02[-0.31,0.35]
Manwaring 2008	30	1.1 (2)	30	0.8 (1.9)		9.52%	0.3[-0.7,1.3]
Total ***	79		78			100%	0.05[-0.26,0.36]
Heterogeneity: $\tau^2=0$; $\chi^2=0.27$, $df=1$ ($P=0.6$); $I^2=0\%$ Test for overall effect: $Z=0.3$ ($P=0.77$)							
Favours warmed/humid CO ₂					-1 -0.5 0 0.5 1	Favours control	

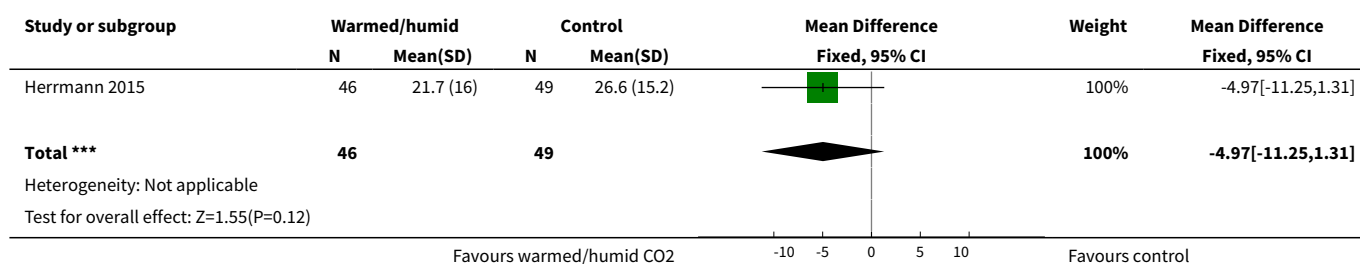
Analysis 6.5. Comparison 6 Warmed +/- humidified CO₂ versus unwarmed and unhumidified CO₂, Outcome 5 Severity of shoulder tip pain at 24 hours post-op.

Study or subgroup	Warmed/humid		Control		Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)			
Herrmann 2015	48	1.2 (2.4)	49	1.6 (3.1)		62.16%	-0.37[-1.46,0.72]
Manwaring 2008	30	3 (2.6)	30	2.1 (2.9)		37.84%	0.9[-0.49,2.29]
Total ***	78		79			100%	0.11[-0.75,0.97]
Heterogeneity: $\tau^2=0$; $\chi^2=1.98$, $df=1$ ($P=0.16$); $I^2=49.56\%$ Test for overall effect: $Z=0.25$ ($P=0.8$)							
Favours warmed/humid CO ₂					-2 -1 0 1 2	Favours control	

Analysis 6.6. Comparison 6 Warmed +/- humidified CO₂ versus unwarmed and unhumidified CO₂, Outcome 6 Severity of shoulder tip pain at 48 hours post-op.

Study or subgroup	Warmed/humid		Control		Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)			
Herrmann 2015	47	1.2 (2.3)	49	1.6 (2.6)		100%	-0.39[-1.36,0.58]
Total ***	47		49			100%	-0.39[-1.36,0.58]
Heterogeneity: Not applicable Test for overall effect: $Z=0.78$ ($P=0.43$)							
Favours warmed/humid CO ₂					-2 -1 0 1 2	Favours control	

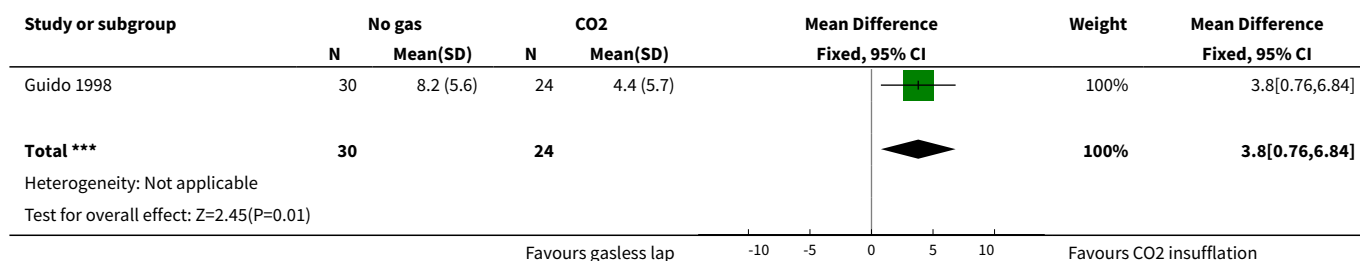
Analysis 6.7. Comparison 6 Warmed +/- humidified CO₂ versus unwarmed and unhumidified CO₂, Outcome 7 Analgesia usage (morphine mg).



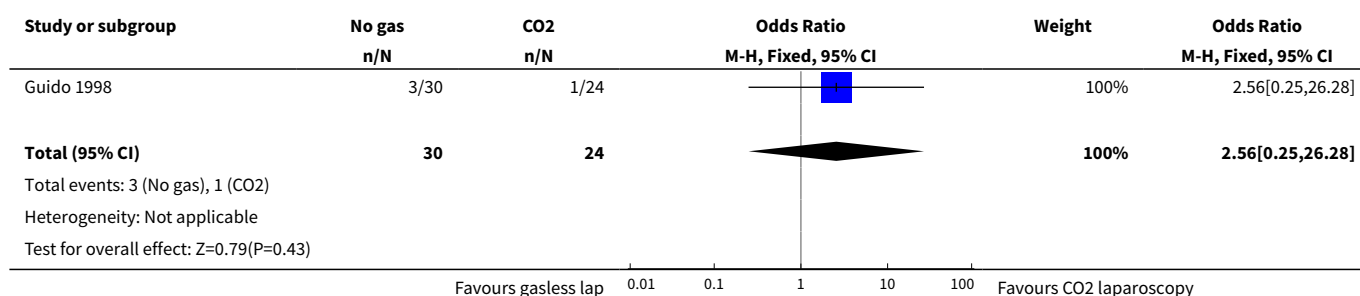
Comparison 7. Gasless laparoscopy versus carbon dioxide insufflation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Severity of STP over 72 hours post-operative	1	54	Mean Difference (IV, Fixed, 95% CI)	3.80 [0.76, 6.84]
2 Adverse events	1	54	Odds Ratio (M-H, Fixed, 95% CI)	2.56 [0.25, 26.28]

Analysis 7.1. Comparison 7 Gasless laparoscopy versus carbon dioxide insufflation, Outcome 1 Severity of STP over 72 hours post-operative.



Analysis 7.2. Comparison 7 Gasless laparoscopy versus carbon dioxide insufflation, Outcome 2 Adverse events.



APPENDICES

Appendix 1. Cochrane Gynaecology and Fertility Group (CGFG) specialised register search strategy

Searched 08 August 2018

PROCITE platform

Keywords CONTAINS "laparoscopic" or "Laparoscopic-Assisted Minilaparotomy" or "laparoscopy" or "laparoscopically assisted hysterectomy" or "laparoscopically assisted vaginal hysterectomy" or "laparoscopy-assisted vaginal hysterectomy" or "hysterectomy, laparoscopically assisted vaginal" or "hysterectomy-laparoscopic" or "gynecological laparoscopic procedure" or "*Surgical-Procedures,-Laparoscopic" or "surgery-gynaecological" or "laparoscopic adnexal surgery" or "laparoscopic chromopertubation" or "laparoscopic hysterectomy" or "laparoscopic myomectomy" or "laparoscopic pelvic surgery" or "laparoscopic ovarian cystectomy" or "laparoscopic pelvic surgery" or "laparoscopic procedure" or "Laparoscopic Surgery" or "laparoscopic surgical treatment" or "laparoscopic treatment" or "laparoscopic tubal ligation" or "diagnostic laparoscopy" or Title CONTAINS "laparoscopic" or "Laparoscopic-Assisted Minilaparotomy" or "laparoscopy" or "laparoscopically assisted hysterectomy" or "laparoscopically assisted vaginal hysterectomy"

AND

Keywords CONTAINS "post-operative pain" or "pain-operative" or "Pain, Postoperative" or "peri-operative pain" or "pain-surgical" or "pain relief" or "pain reduction" or "Pain Management" or "pain-control" or "shoulder pain" or Title CONTAINS "post-operative pain" or "pain-operative" or "Pain, Postoperative" or "peri-operative pain" or "pain-surgical" or "pain relief" or "pain reduction" or "Pain Management" or "pain-control" or "shoulder pain" (201 hits)

Appendix 2. CENTRAL CRSO search strategy

Searched 08 August 2018

Central Register of Studies Online

Web platform

#1 MESH DESCRIPTOR Hand-Assisted Laparoscopy EXPLODE ALL TREES 10

#2 MESH DESCRIPTOR Laparoscopy EXPLODE ALL TREES 4932

#3 laparoscop* 13960

#4 postlaparoscop* 26

#5 gyn?ecologic adj5 endoscop* 33

#6 #1 OR #2 OR #3 OR #4 OR #5 13984

#7 shoulder* adj5 pain* 2266

#8 Diaphragm* adj5 irritat* 12

#9 Diaphragm* adj5 pain* 30

#10 #7 OR #8 OR #9 2290

#11 MESH DESCRIPTOR Pain, Postoperative 12823

#12 #10 AND #11 213

#13 #10 OR #12 2290

#14 #6 AND #13 326

Appendix 3. MEDLINE search strategy

From 1946 to 08 August 2018

OVID platform

1 exp Laparoscopy/ or exp Hand-Assisted Laparoscopy/ (88051)

- 2 Laparoscop*.tw. (112254)
- 3 post-laparoscop\$.tw. (244)
- 4 Laparoscopy/ae [Adverse Effects] (10714)
- 5 exp Gynecologic Surgical Procedures/ and Laparoscop*.tw. (8707)
- 6 (gyn?ecologic adj5 endoscop*).tw. (206)
- 7 postlaparoscop*.tw. (110)
- 8 or/1-6 (125827)
- 9 (shoulder\$ adj3 pain*).tw. (8342)
- 10 Shoulder/ and pain.tw. (1737)
- 11 Diaphragm/ and pain.tw. (318)
- 12 (Diaphragm\$ adj3 irritat*).tw. (30)
- 13 (Diaphragm\$ adj3 pain*).tw. (65)
- 14 postoperative pain/ and laparoscop*.tw. (2934)
- 15 (postoperative pain and laparoscop*).tw. (3287)
- 16 (intraperitoneal anaesth* or intraperitoneal analgesi*).tw. (11)
- 17 pulmonary recruitment manoeuvre*.tw. (5)
- 18 ((humidified adj3 gas*) or (warm* adj3 gas)).tw. (345)
- 19 (fluid* adj5 instillation*).tw. (328)
- 20 (Intraperitoneal adj3 instillation*).tw. (299)
- 21 (peritoneal adj3 instillation).tw. (57)
- 22 (Intraperitoneal adj3 nebulization).tw. (8)
- 23 (peritoneal adj3 nebulization).tw. (4)
- 24 (insufflation adj3 humidif*).tw. (80)
- 25 gasless laparoscop*.tw. (246)
- 26 heated carbon dioxide.tw. (11)
- 27 warmed carbon dioxide.tw. (3)
- 28 CO2 pressure*.tw. (576)
- 29 carbon dioxide pressure*.tw. (721)
- 30 (insufflation adj3 pressure*).tw. (588)
- 31 (trocar adj5 infiltration).tw. (32)
- 32 (force* adj3 evacuation).tw. (68)
- 33 (fluid* adj3 displacement).tw. (321)
- 34 inflation breath*.tw. (12)
- 35 head down tilt.tw. (1116)
- 36 intraperitoneal drain*.tw. (149)
- 37 (gas adj3 drain*).tw. (80)
- 38 (intraperitoneal adj3 ropivacaine).tw. (41)
- 39 (ropivacaine adj3 infiltration).tw. (151)
- 40 (manoeuvre adj3 (shoulder adj3 pain)).tw. (1)
- 41 transversus abdominis plane block*.tw. (555)
- 42 (continuous infusion adj3 anaesthetic).tw. (16)
- 43 pneumoperitoneum pressure*.tw. (79)
- 44 or/9-43 (19619)
- 45 exp Cholecystectomy, Laparoscopic/ or Cholecystectomy/ (27145)
- 46 Cholecystectom\$.tw. (26462)
- 47 exp Hernia/ (71703)
- 48 exp Colorectal Surgery/ (2936)
- 49 Colorectal.tw. (126326)
- 50 exp Nephrectomy/ (32215)
- 51 nephrectomy.tw. (29452)
- 52 renal.tw. (541248)
- 53 colectom\$.tw. (10759)
- 54 herni\$.tw. (70272)
- 55 gastric.tw. (227577)
- 56 exp Appendectomy/ (10255)
- 57 Appendectom\$.tw. (8463)
- 58 bariatric.tw. (14887)
- 59 exp Prostatectomy/ (28735)
- 60 Prostatectom\$.tw. (27412)
- 61 or/45-60 (1089951)
- 62 randomized controlled trial.pt. (465864)
- 63 controlled clinical trial.pt. (92545)

64 randomized.ab. (418196)
65 randomised.ab. (83485)
66 placebo.tw. (195937)
67 clinical trials as topic.sh. (184341)
68 randomly.ab. (294962)
69 trial.ti. (185706)
70 (crossover or cross-over or cross over).tw. (77227)
71 or/62-70 (1222523)
72 exp animals/ not humans.sh. (4482204)
73 71 not 72 (1125610)
74 8 and 44 and 73 (2156)
75 74 not 61 (729)

Appendix 4. Embase search strategy

From 1980 to 08 August 2018

OVID platform

1 exp gynecologic surgery/ and Laparoscop*.tw. (18696)
2 (gyn?ecologic adj5 endoscop*).tw. (256)
3 exp Laparoscopy/ or exp Hand-Assisted Laparoscopy/ (127498)
4 laparoscop\$.tw. (166410)
5 postlaparoscop*.tw. (121)
6 or/1-5 (191176)
7 (shoulder* adj3 pain*).tw. (10130)
8 shoulder pain/ (12598)
9 Diaphragm/ and pain.tw. (1125)
10 postoperative pain/ and laparoscop\$.tw. (6661)
11 (postoperative pain and laparoscop\$).tw. (4863)
12 (intraperitoneal anaesth* or intraperitoneal analgesi*).tw. (21)
13 pulmonary recruitment manoeuvre*.tw. (6)
14 (intraperitoneal adj3 ropivacaine).tw. (65)
15 (ropivacaine adj3 infiltration).tw. (185)
16 (manoeuvre adj3 (shoulder adj3 pain)).tw. (1)
17 (fluid* adj3 displacement).tw. (342)
18 intraperitoneal drain*.tw. (159)
19 inflation breath*.tw. (20)
20 (gas adj3 drain*).tw. (103)
21 (intraperitoneal adj3 ropivacaine).tw. (65)
22 head down tilt.tw. (1154)
23 (force* adj3 evacuation).tw. (72)
24 ((humidified adj3 gas*) or (warm* adj3 gas)).tw. (385)
25 (fluid* adj5 instillation*).tw. (381)
26 (Intraperitoneal adj3 instillation*).tw. (319)
27 (peritoneal adj3 instillation).tw. (78)
28 (Intraperitoneal adj3 nebulization).tw. (17)
29 (peritoneal adj3 nebulization).tw. (8)
30 (insufflation adj3 humidif*).tw. (91)
31 (insufflation adj3 pressure*).tw. (686)
32 gasless laparoscop*.tw. (309)
33 heated carbon dioxide.tw. (10)
34 carbon dioxide pressure*.tw. (707)
35 warmed carbon dioxide.tw. (5)
36 (trocar adj5 infiltration).tw. (38)
37 transversus abdominis plane block*.tw. (759)
38 (continuous infusion adj3 anaesthetic).tw. (27)
39 pneumoperitoneum pressure*.tw. (134)
40 CO2 pressure*.tw. (727)
41 or/7-40 (30928)
42 exp cholecystectomy/ (40073)
43 Cholecystectom\$.tw. (33117)
44 exp hernia/ (85235)

45 exp colorectal surgery/ (17358)
 46 Colorectal.tw. (176599)
 47 exp nephrectomy/ (52212)
 48 nephrectomy.tw. (39664)
 49 renal.tw. (650579)
 50 colectom\$.tw. (16090)
 51 herni\$.tw. (74502)
 52 gastric.tw. (260452)
 53 exp appendectomy/ (15814)
 54 Appendectom\$.tw. (9849)
 55 bariatric.tw. (26311)
 56 exp prostatectomy/ (47317)
 57 Prostatectom\$.tw. (41063)
 58 or/42-57 (1310620)
 59 Clinical Trial/ (939611)
 60 Randomized Controlled Trial/ (483051)
 61 exp randomization/ (79343)
 62 Single Blind Procedure/ (30237)
 63 Double Blind Procedure/ (140917)
 64 Crossover Procedure/ (53215)
 65 Placebo/ (294665)
 66 Randomized controlled trial\$.tw. (167934)
 67 Rct.tw. (27034)
 68 random allocation.tw. (1683)
 69 randomly allocated.tw. (28338)
 70 allocated randomly.tw. (2260)
 71 (allocated adj2 random).tw. (779)
 72 Single blind\$.tw. (20015)
 73 Double blind\$.tw. (175062)
 74 ((treble or triple) adj blind\$.tw. (696)
 75 placebo\$.tw. (257904)
 76 prospective study/ (418409)
 77 or/59-76 (1818422)
 78 case study/ (53565)
 79 case report.tw. (328576)
 80 abstract report/ or letter/ (956048)
 81 or/78-80 (1330420)
 82 77 not 81 (1772483)
 83 (exp animal/ or animal.hw. or nonhuman/) not (exp human/ or human cell/ or (human or humans).ti.) (5283915)
 84 82 not 83 (1706172)
 85 6 and 41 and 84 (3154)
 86 85 not 58 (1100)

Appendix 5. PsycINFO search strategy

From 1806 until 08 August 2018

OVID platform

1 Laparoscop\$.tw. (457)
 2 post-laparoscop\$.tw. (1)
 3 post operative pain.tw. (181)
 4 post laparoscopic pain.tw. (0)
 5 (shoulder\$ adj3 pain\$.tw. (563)
 6 (shoulder\$ adj3 tip\$.tw. (2)
 7 (muscle\$ adj3 pain\$.tw. (1228)
 8 postoperative pain.tw. (1162)
 9 (Pain adj3 laparoscop\$.tw. (22)
 10 exp Gynecological Disorders/ (1702)
 11 or/3-10 (4734)
 12 1 or 2 (457)
 13 11 and 12 (62)

Appendix 6. CINAHL search strategy

From 1961 to 08 August 2018

EBSCO platform

#	Query	Results
S19	S6 AND S18	80
S18	S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17	1,248,909
S17	TX allocat* random*	8,980
S16	(MH "Quantitative Studies")	20,103
S15	(MH "Placebos")	10,820
S14	TX placebo*	51,784
S13	TX random* allocat*	8,980
S12	(MH "Random Assignment")	50,305
S11	TX randomi* control* trial*	151,895
S10	TX ((singl* n1 blind*) or (singl* n1 mask*)) or TX ((doubl* n1 blind*) or (doubl* n1 mask*)) or TX ((tripl* n1 blind*) or (tripl* n1 mask*)) or TX ((trebl* n1 blind*) or (trebl* n1 mask*))	967,731
S9	TX clinic* n1 trial*	226,567
S8	PT Clinical trial	86,036
S7	(MH "Clinical Trials+")	242,979
S6	S4 AND S5	114
S5	TX Shoulder* N3 Pain*	5,657
S4	S1 OR S2 OR S3	26,604
S3	TX postlaparoscop*	25
S2	TX laparoscop*	26,602
S1	(MM "Laparoscopy") OR (MH "Surgery, Laparoscopic")	13,127

CONTRIBUTIONS OF AUTHORS

Mr Philip Kaloo wrote the protocol and screened the abstracts, extracted and input data and assisted in writing the full review.

Dr Sarah Armstrong screened the abstracts, extracted and input data and wrote the first draft of the review.

Dr Claire Kaloo commented on and approved the draft protocol and assisted in writing the full review with particular focus on anaesthetic issues.

Dr Vanessa Jordan commented on the draft full review.

DECLARATIONS OF INTEREST

PK has no known conflicts of interest.

SA has no known conflicts of interest.

CK has no known conflicts of interest.

VJ has no known conflicts of interest.

SOURCES OF SUPPORT

Internal sources

- None, Other.

External sources

- None, Other.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

It became apparent that the intervention of the application of intraperitoneal local anaesthetic was broadly divided into two very different groups. One was local anaesthetic to the subdiaphragmatic area, and the other was local anaesthetic to the rest of the peritoneal cavity. We therefore felt that instead of combining these different interventions into one group, and subgrouping subdiaphragmatic local anaesthetic, that we would separate them into their own comparisons.

We decided that it would be important to subgroup specific interventions within a broad comparison group. For example, there were a number of studies that utilised the pulmonary recruitment manoeuvre as the intervention within the comparison 'specific versus standard technique for releasing the pneumoperitoneum'. Therefore we altered the methods to reflect the ability to subgroup interventions with more than one study in order to examine the specific effect of that particular intervention.

The wording of data synthesis has changed slightly since writing the protocol. Instead of placebo versus intraperitoneal local anaesthetic, we have changed the comparison to no local anaesthetic versus intraperitoneal local anaesthetic. This is to include studies that did not offer placebo as a control.

We decided that analgesia usage was an important secondary outcome to both women and clinicians. Therefore it has been included in the summary of findings tables.

INDEX TERMS

Medical Subject Headings (MeSH)

Acetaminophen [therapeutic use]; Analgesics [therapeutic use]; Anti-Inflammatory Agents, Non-Steroidal [therapeutic use]; Carbon Dioxide [administration & dosage]; Diclofenac [therapeutic use]; Drainage [adverse effects]; Gynecologic Surgical Procedures [*adverse effects]; Gynecological Examination [*adverse effects] [methods]; Incidence; Insufflation [methods]; Laparoscopy [*adverse effects] [methods]; Meperidine [therapeutic use]; Pain Measurement; Pain, Procedural [epidemiology] [etiology] [*prevention & control]; Pirinitramide [therapeutic use]; Pneumoperitoneum [surgery]; Randomized Controlled Trials as Topic; Shoulder Pain [epidemiology] [etiology] [*prevention & control]

MeSH check words

Female; Humans